U. S. Food and Drug Administration
Center for Food Safety and Applied Nutrition
National Advisory Committee on Microbiological Criteria for Foods
December 8-10, 1999

National Advisory Committee on Microbiological Criteria for Foods

Meeting on Fresh Citrus Juice

Transcript of Proceedings

Volume I: Wednesday, December 8, 1999
Volume II: Thursday, December 9, 1999
Volume III: Friday, December 10, 1999

Volume I
Wednesday, December 8, 1999

PARTICIPANTS

COMMITTEE MEMBERS

James D. Anders
Dane T. Bernard
Robert L. Buchanan
James S. Dickson
Catherine W. Donnelly
Michael P. Doyle
Mel W. Eklund
Daniel L. Engeljohn, Ph.D.
Michael G. Groves
Michael L. Jahncke
John M. Kobayashi
Earl G. Long
Roberta A. Morales DVM, Ph.D.
Nancy E. Nagle
Marguerite A. Neill
Alison D. O'Brien
Michael C. Robach
Leon H. Russell, Jr.
Skip Seward II
William H. Sperber
William H. Sveum
Bala Swaminathan, Ph.D.

Robert B. Tompkin

AGENCY REPRESENTATIVES

Janice Oliver, Deputy Director, Center for Food Safety and Applied Nutrition, FDA
Dr. Morris E. Potter, Vice Chair
Arthur P. Liang, MD, MPH, CDC Liaison
Lee Anne Jackson, FDA Liaison
E. Spencer Garrett, Commerce Department Liaison
LTC Scott Severin, Defense Department Liaison
Dr. Karen Hulebak, Executive Secretary
Jacque Knight, Advisory Committee Specialist

ALSO PRESENT

Dr. Larry Beuchat, University of Georgia

CONTENTS

AGENDA ITEM PAGE

- Adjournment

PROCEEDINGS

MS. OLIVER: Good morning, everyone.

I'm Janice Oliver and I'm Deputy Director for the Center for Food Safety and Applied Nutrition. I'd like to thank the Committee members and our invited experts for making themselves available for the meeting.

Over the next two days, we're going to have data that will be presented on production practices and safety issues associated with fresh citrus juice, and we're asking the Committee to provide us with sound scientific recommendations on how FDA can assure th safety of fresh citrus juice.

We're not here to discuss specific juice outbreaks nor any policy matters. We're askin the Committee for your scientific input on performance criteria for the fresh citrus j industry. And specifically the Committee is being asked to provide us recommendations two areas: the internalization and survival of pathogens, and the application and measurement of the 5-log reduction standard.

I'm going to read specifically the questions that are posed to the Committee, and you should also have a copy. The questions posed to the Committee are:

On the internalization and survival of pathogens, is it valid to assume that there is no internalization of pathogens in citrus fruit?

Is internalization of pathogens into citrus fruit theoretically possible?

If internalization of pathogens into citrus fruit is theoretically possible, is such internalization likely to result in a public health risk?

And the last on internalization, if internalization does occur and it results in a public health risk, are there techniques to assure that internalization of pathogens d not occur? And if so, what are they?

The second group of questions we have deal with the application and measurement of the 5-log reduction standard.

At what point in the production process should a processor begin to measure attainment of the 5-log pathogen reduction? For example, should fruit be cleaned and culled befor measurement of the 5-log reduction has begun? And are there limits within which the 5- reduction must be accomplished?

Would using cumulative steps that are separated in time and location impact a processor's ability to achieve and deliver a 5-log reduction?

Can the safety achieved by the 5-log reduction be maintained consistently if a processor does not package product immediately after attaining the 5-log reduction?

These are the issues we'd appreciate your input on.

I want to make a number of announcements now and talk about some of the ground rules for the meeting for the Committee and especially for those in attendance here.

Dr. Wachsmuth may not be able to attend the meeting. She may be able to attend a portion of it. She sends her apologies if she is not able to be here, and, therefore, will chair the meeting in her absence.

Second, if you look over the agenda, you will note references to questions of

clarification. This time is reserved for the Committee and our invited expert, Dr. Lar Beuchat of the University of Georgia, to ask questions of the various presenters. The purpose of this is to provide answers to specific points that were raised during the presentation and to clarify those points for the Committee members. And as a courtesy, questions may be taken from the floor if time permits. But so all are aware, the time not intended to be used to debate issues, and the time is not intended to be used to r subjects that were not a part of the discussion. They are questions of clarification.

The Chair reserves the right to suspend the time allotted or to limit it for the questions of clarification if the conduct of the meeting is adversely affected.

I would also say that the Committee will have time tomorrow also to ask additional questions of all of the presenters who will be here tomorrow to answer any additional questions that you may have.

Third, there is a public comment period at the end of the day, and for those who preregistered to make a public statement this afternoon, I remind you that your time i

limited to five minutes, and I will once again remind you in the afternoon. But if you not register by December 1st, we may be able to take additional comments, but your tim will most likely be limited then to two minutes.

Lastly, Thursday's program, tomorrow's program, is reserved exclusively for the Committee to discuss the issues and formulate the recommendations or the response to questions that have been posed by FDA. The recommendations must be finalized tomorrow. There is a very full agenda on Friday on the presentation and discussion of FFSIAS E. 0157:H7, so we need to finish the issue on juice tomorrow.

They are the basic ground rules. One other thing I would like to remind people is that today's session, as the rest of the Committee, will be transcribed. So if anybody is asking questions, if you could please say your name before asking them, it would reall help our transcriber, and I will try to remind people during the session.

Now what I'd like to do in the interest of time is to ask each of the Committee member to introduce yourself and to give yourself a short introduction, if possible, so we ca get through the agenda. I'll start at that end. Bruce?

DR. TOMPKIN: I'm Bruce Tompkin with ConAgra Refrigerated Prepared Foods.

MR. LONG: Earl Long, Center for Infectious Diseases, CDC.

MR. BERNARD: Dane Bernard, National Food Processors Association.

MR. SEWARD: Skip Seward, McDonald's Corporation.

DR. KVENBERG: John Kvenberg, Food and Drug Administration.

MS. NAGLE: Nancy Nagle, Nagle Resources.

MR. ROBACH: Mike Robach, Conti Group Companies.

MR. DOYLE: I'm Mike Doyle of the University of Georgia.

DR. HULEBAK: I'm Karen Hulebak, Food Safety and Inspection Service, and Executive Secretary of this Committee.

DR. TROXELL: Terry Troxell, CFSAN.

MS. JACKSON: LeeAnne Jackson, FDA, CFSAN.

DR. LIANG: Art Liang, CDC, Food Safety Initiative.

LTC SEVERIN: Scott Severin, Army Office of the Surgeon General.

MR. ANDERS: Jim Anders, North Dakota Health Department Laboratories.

DR. SWAMINATHAN: Bala Swaminathan, CDC, Foodborne and Diarrheal Diseases Branch.

MR. BUCHANAN: Bob Buchanan, Food and Drug Administration, CFSAN.

MR. SPERBER: Bill Sperber, Cargill.

MR. GROVES: Mike Groves, LSU School of Veterinary Medicine.

MS. O'BRIEN: Alison O'Brien, Uniformed Services University of the Health Sciences, Bethesda.

MR. KOBAYASHI: John Kobayashi, Washington State Health Department.

MR. JAHNCKE: Mike Jahncke, Virginia Tech.

MS. DONNELLY: Cathy Donnelly, University of Vermont.

MR. SVEUM: Bill Sveum, Campbell's Soup Company.

MR. RUSSELL: Leon Russell, Texas A&M University.

DR. BEUCHAT: Larry Beuchat, University of Georgia.

MS. OLIVER: Thank you very much.

I'd like to introduce the first presenter next, but before I do that, I just want to remind all of the presenters that you've all been given the times for your presentatio and we are going to have a timekeeper and keep people to their times because we have a very full agenda to the end of the day, and we have lots of people that are signed up public comment.

So our first speaker on the previous recommendations and rulemaking is Dr. John Kvenberg, Deputy Director, Office of Field Programs, FDA Center for Food Safety and Applied Nutrition. John?

DR. KVENBERG: Good morning, everyone. As Ms. Oliver mentioned in the talk, my presentation is, if you will, the history of events on juice to include the National Advisory Committee recommendations and rulemaking.

After the October 1996 apple juice outbreak from E. coli 0157:H7, FDA held a public

meeting on December 16th and 17th of 1996 to consider the safety of all juices in ligh the information and discussion provided during the public meeting on current science a technology on fresh juices.

The Fresh Produce Subcommittee of this National Advisory Committee on Microbiological Criteria for Foods attended the public meeting and made recommendations to the full Committee. The Subcommittee risk conclusions were based on documented outbreaks of ill association with consumption of contaminated juices. These data were presented and discussed during the open public meeting.

Based on the information presented at the meeting and on the Subcommittee's expertise, the Committee made several recommendations. The Committee concluded that: number one, history of public health problems associated with fresh juice indicated a need for act safety interventions; and, two, for some fruit--for example, oranges--the need for intervention may be limited to surface treatment, but for others--for example, apples

products--additional interventions may be required, for example, pasteurization or treatment of the juice.

In addition, the Committee recommended to FDA the use of safety performance criteria instead of mandating the use of a specific intervention technology, such as thermal processing.

At the time the Committee recommended that an adequate level of safety could be achieved by requiring interventions that have been validated to achieve a cumulative 5 reduction in the target pathogen or the risk reduction in yearly risk of illness to 10 assuming consumption of 100 milliliters of juice daily.

Finally, the Committee stated that HACCP and safety performance criteria should form the general conceptual framework to ensure the safety of juices and that control measu should be based on a thorough hazard analysis with validation of the process as an integral part of the framework.

Based in part on these recommendations, in the Federal Register of April 24, 1998, FDA proposed to adopt regulations to assure the safe and sanitary processing of fruit and vegetable juices. In the proposed HACCP rule, FDA tentatively concluded that a prevent system such as HACCP appears to offer the most effective way to control the significan microbial hazards along with other hazards that represent juice-associated health problems.

In addition, in the Federal Register of July 8, 1998, FDA published a final rule requiring that juice products not specifically processed to inactivate 5 logs of harmf bacteria bear a warning statement informing consumers of the potential risk of foodbor illness associated with the product.

To avoid the warning statement, juice manufacturers must process juice in a manner tha will achieve a 5-log reduction in the most pertinent microorganism of public health concern. However, certain citrus juice processors who applied for an extension were allowed additional time before the labeling requirement became effective to develop an validate intervention measures that achieved the 5-log pathogen reduction standard.

Also, FDA held two technical scientific workshops in November of 1998 in Florida and i California to discuss and clarify issues related to the implementation of the agency's rule requiring a warning statement for certain juice products. In particular, the work addressed the pathogen reduction interventions that had been developed for citrus juic production and methods for measuring and validating such systems. The 5-log reduction performance standard that the Committee recommended also has been tentatively included the proposed HACCP rule as a mandatory component of a valid HACCP system.

As Dr. Troxell will outline later, the agency will once again be relying on the Committee's expertise and recommendations as it proceeds in its consideration of HACCP requirements for juice and juice products.

To explore the use of HACCP in the production of juice and juice products, the agency has been conducting a HACCP pilot program with selected juice manufacturers in the con of the agency's manufacturing HACCP pilot program. To date, three manufacturers of jui and juice products have been involved in this HACCP endeavor. They are Ocean Spray Cranberries, Orchid Island Juice Company, and Fresh Samantha.

Ocean Spray Cranberries and Fresh Samantha pasteurize their juice, while Orchid Island Juice Company is a fresh citrus juice producer. Our next presenter will share some of observations and comments related to the HACCP pilot program with the firm.

Thank you.

MS. OLIVER: Thanks, John.

As John mentioned, our next presenters will talk about the juice HACCP pilot program, and the presenters are: MaryGrace Sexton and John Martinelli from Orchid Island Juice Company, and Dr. Donna Garren from United Fresh Fruit and Vegetable Association.

MS. SEXTON: Good morning. Sometimes a visual, I think, is more effective than not seeing this, but I really do want everybody to take--can everybody see this? Okay.

I'm MaryGrace Sexton with the FDA pilot plant for fresh squeezed citrus juices for the United States of America. Orchid Island Juice Company has been in business for 10 year successfully satisfying the customers and providing a safe product consistently. You w get the statistics of biological testing by a scientist. Mr. Martinelli is here to ass me in representing the FDA pilot program in the absence of the FDA.

We requested that the FDA present the information about the pilot program, but they refused. They said their goal was to see if a HACCP plan could be implemented in fresh squeezed juices as it was done in fish. Their outcome was positive, and they were happ say that it is possible.

I need to remind you that E. coli 0157:H7 has never been in fresh squeezed citrus juices and never has ever been considered to be on the inside of the orange on the tre We feel the FDA pilot program could be better utilized if you would direct questions a visits to the plant. We would have been able to inform you that fresh squeezed citrus processors do not immerse fruit.

Two years ago, the same Committee requested that we go achieve a 5-log reduction in th killer organism E. coli 0157:H7. We have shown the FDA that we can achieve a 6.7-log reduction.

We have made recommendations to the FDA and the USDA inspection services. The State of Florida is the only one that is regulated. They require that the Florida Department of Agriculture test all incoming fruit for integrity and fruit maturity standards. In the State of Florida, it is mandatory that a commercial fresh squeezed citrus plant have continuous on-site USDA inspection. If this is an issue between the agencies, it does constitute holding up the process of initiating a mandatory inspection for all fresh squeezed processors in the United States of America. How can you outlaw a product befo you place mandatory inspection on the entire country, not one State?

Processors in question have a plant on the East Coast and a plant on the West Coast. Only the uninspected, the unregulated plants contaminate the product. This is an indication that continuous on-site USDA inspection is productive. This is an indicatio that it is not the process, it is the processor.

We will show you technology available to make fresh squeezed citrus juice safe. I am not making light of food safety issues in America. I am trying to bring to your attent this is one that can be resolved by placing regulatory standards in place to verify complete safety to the consumer. Pasteurization is not a cure-all for the juice indust

I want to invite our next speaker to our processing facility to address her concerns and the concerns of the organization she represents. The science you will be exposed t will be of wide range, some indicative of the industry and some forced science to prov point that has never, ever occurred.

But you, ladies and gentlemen, are of the best scientific minds regarding this matter, so who better than you to listen to the following information? And I ask personally th you do not consider redefining the word "fresh" for the convenience of other processes. Fresh to the consumer means fresh.

MR. MARTINELLI: Good morning. I'm John Martinelli with the Orchid Island Juice Company

The Orchid Island Juice Company has been in business for 10 years now, and we are one of the conscientious fresh squeezed juice producers in the United States of America to

We are also the Food and Drug Administration's pilot program, and in our documentation our presentations today, you will hear reference to the Florida inspection process.

In the State of Florida, we have two inspectors in our facility at all times. The Florida Department of Agriculture checks our fruit for maturity and wholesomeness. The randomly sample it, and it is a zero tolerance on unwholesome fruit.

The USDA randomly samples our product for quality and for packaging and labeling infractions. We microbially test every batch of juice at Orchid Island Juice Company's facility.

Because of our commitment to our customers to squeeze our fresh oranges within 24 hour of when they are picked, we have also installed a satellite monitor so that we can mon any weather patterns that might be detrimental to that effort.

The first critical control point at Orchid Island Juice Company is preoperational sanitization. We swab-test fruit contact surfaces as well as juice contact surfaces fo microbial activity. Strategically placed in our facility, we also have hand-sanitizing stations. Every associate on the production line is required to sanitize their hands before reporting to their workstation.

Our processing facility is also roped off from any uninvited guests or people who shouldn't be in the processing area.

The second critical control point at Orchid Island Juice Company is fruit acceptability. Our fruit acceptability requirement--and all of our harvesters know this--is there will be no dropped fruit and no unwholesome fruit in a trailer load, or will be rejected.

As the fruit comes into the processing line at Orchid Island Juice Company, we high-pressure spray it and saturate it with sanitizer.

Throughout the entire facility, our processing equipment is doused in sanitizer throughout the entire day to inhibit microbial growth of any kind.

When the Department of Citrus regulated fresh orange juice, one thing that they mandated is that there had to be 60 seconds' worth of contact time in the scrubbing an sanitizing aspect of the fruit. We installed a double-stack scrubber to facilitate tha seconds.

Another thing that the Department of Citrus mandated--or suggested was a fruit return belt. This fruit return belt, if any piece of fruit misses an extractor, the fruit is automatically reintroduced into the beginning of the sanitizing process and regraded before it goes back to the extractors.

Borrowing technology from the fresh fruit industry, Orchid Island Juice Company has installed a high--pressure sprayer. This high-pressure sprayer produces 300 pounds per square inch which accentuates any defects in skin surface problems and makes it much, easier to grade the fruit out.

Then the fruit is rinsed, and then another sanitizer is added to it on the final washing bed. On the final washing bed, we have also installed a top brush washer, and top brush washer slows down the process of the fruit and increases the agitation for t surface contact.

The Department of Citrus recommends scallop brushes so that the fruit doesn't turn on just one axis, but has a tendency to tumble across the washer beds. All of the washer at Orchid Island Juice Company are scallop brushes.

Our third critical control point at Orchid Island Juice Company is the grading. Gradin is essential in a fresh squeezed juice operation, especially in the State of Florida s

the Florida Department of Agriculture allows zero tolerance when it comes to defective unwholesome fruit in fresh squeezed orange juice.

Our critical control limit on our graders is 12 graders on the line at any given time with four fruit inspectors. The four fruit inspectors are responsible; if, in fact, an the sanitizer dilution alarms go off, they are to stop the line immediately and make a adjustment. They are also responsible for stopping the line if, in fact, the volume of fruit is incorrect.

Our fourth critical control point is our sanitizer alarm system. These are audible as well as visual alarms, and the limits are set far above the recommended dilutions.

We rinse the fruit and then send the fruit to our extractor room. The extractor room i enclosed, and the thermostats are set at 40 degrees. That's another recommendation by Department of Citrus.

Our juice is extracted from the orange and within seconds is reduced below 34 degrees.

A Food and Drug Administration--not a requirement but a recommendation was for positiv pressurization of our lines. So what we did was we--so if there was any transport of j or cooling solution, it would be from the juice side to the cooling side, and not the inverse.

We send it to our tanks, and then we bottle our juice in sanitary rooms, once again, enclosed and set at 40 degrees.

Randomly throughout the day, the USDA inspectors--because we carry the Florida sunshin tree on our juice, the USDA inspectors are required by the Department of Citrus to che our juice, once again, for quality and packaging requirements.

At the end of each day, we hand-clean the facility. Then we CIP all the processing equipment in the facility, and borrowing technology from the meat-packing industry, we foaming caustic all of our fruit contact surfaces. Then we rinse the surfaces with sanitized potable city water, and at that point in time, Orchid Island Juice Company contends that our juice, our processing facility is, once again, ready for use the nex day.

The Orchid Island Juice Company adheres strictly to the Florida model of inspections, and as you see when you walked through our facility, there was no immersion whatsoever And in the 10 years of doing business at Orchid Island Juice Company, we've served ove 350 million servings of juice, and over 1 billion pieces of fruit have passed through processing line, and there has never been a detection of a human pathogen in our produ

Dr. Garren?

DR. GARREN: Good morning. My name is Donna Garren with the United Fresh Fruit and Vegetable Association. I would like to thank MaryGrace and John for sharing their time this morning with me.

We represent the interests of growers and distributors of fresh juice and produce in general. I would like to provide comments on preliminary studies reporting the potenti internalization or infiltration of pathogens into citrus fruit.

Based on current preliminary internalization research conducted by the Food and Drug Administration, we believe it is premature for this Committee to reconsider its origin recommendation of proposing 5-log performance standards to ensure the safety of fresh citrus juices or to not recommend mandatory preventative technology such as pasteurization. Supplementary research suggesting infiltration of pathogens into other produce items, such as tomatoes and apples, does not necessarily support the assumptio that infiltration of pathogens can occur in citrus fruit.

Preliminary internalization research on citrus fruit also did not reflect current industry practices, such as a 10-minute immersion of citrus fruit in a dump tank, whic does not occur in citrus intended for juicing. Also, the use of dye to represent the potential for pathogen incorporation into citrus may not be an appropriate surrogate t the pathogens of concern.

Decisions made by this Committee need to be based on sound science which truly reflect and assess industrial practices and result in fresh juice products. We encourage the development of more research based on current industry control practices before this Committee assesses the potential risks associated with pathogen infiltration into citr fruit prior to juicing.

We also believe that research data generated by the fresh juice industry indicating th infiltration of pathogens of concern is not likely to occur when control measures are strictly applied be seriously considered by this Committee and the Food and Drug Administration.

Thank you for this opportunity to address the Committee.

MS. OLIVER: Thank you very much.

Next, Ms. Laurie Girand will present consumer concerns. She is the program leader for juice safety for STOP, Safe Tables Our Priority.

MS. GIRAND: Could we turn off the slide projector?

Thank you very much. Three years ago, in December of 1996, many of those here were invited to Washington, D.C., to discuss the state of unpasteurized juice. I remember t time vividly because when I learned that no juice victims had been notified or invited cried.

Shortly thereafter, I joined a not-for-profit organization called STOP, Safe Tables Ou Priority, which consists of victims of foodborne illness, their families and friends, are committed to ensuring that the foodborne tragedies they have experienced are not needlessly repeated.

My own intimate association with juice safety began in the fall of 1996 when my husban and I returned different from our parents-only vacation and our only daughter, a 3-year-old, had had diarrhea with stomach cramps for four days. My mother had told us she had bought a couple of quarts of Odwalla apple juice while we were gone and that A had really liked it. In the night, the cramps would cause Anna to awaken in agony screaming. During the day, she would lie listless in my lap, moaning, "My tummy hurts, my tummy hurts."

Because she was refusing to drink, her doctor asked us to push fluids, so we bought Anna more Odwalla apple juice. After all, the company slogan was, "Drink it and thrive." It wasn't until the eighth day of her illness, when Anna was finally hospitalized, that the doctors first told us of E. coli 0157:H7.

On the tenth day of Anna's illness, they discontinued fluids of all kinds because her kidneys were failing and she was beginning to swell. They had to cut off her hospital bracelets because they were becoming constricting. She would beg us for water, but we could only give her one swallow per hour. Her lips became cracked and bloody, her spee slurred. Her urine turned what they call tea-colored.

Then, because of an allergic reaction, doctors stopped her first transfusion, and we waited another 15 hours before they started a second. And then the face of death came visit my only child, my baby girl.

From the anemia, her lips and gums turned gray, her puffy face was ashen, and her bloc work indicated that she should be dialyzed.

Ultimately, our daughter was discharged, but we will never have the good fortune to be able to describe her as recovered. People who recover or who appear to recover from th initial HUS illness are at risk of developing chronic conditions such as complete kidn failure even a decade later. At least four of the surviving Odwalla children presently suffer from gastrointestinal ailments that suggest their colons have not recovered. Ov half of the 70 Odwalla victims were under the age of 6. Another toddler named Anna die that outbreak.

Oh, great. Well, this was a slide with lots of outbreaks on it.

When I learned that these children had been poisoned by unpasteurized juice and that government and industry had known it was possible that this would happen again, I was outraged. Parents should not be misled into believing that unpasteurized beverages are healthier for their children. Here, on the cusp of the millennium, with technology rea available, no one should have to die from drinking juice. Yet less than two months ago three children's lives hung in the balance again from HUS caused by contaminated, unpasteurized apple juice.

But today we're not here to rehash apple juice. We're here because the citrus industry has wanted to convince the FDA that orange juice is somehow different than apple juice fact, the two are different. In 1999 alone, unpasteurized orange juice has caused the largest identified unpasteurized juice outbreaks in the world. This was supposed to be list of known unpasteurized citrus juice outbreaks caused by U.S. producers in the Uni States. This data does not include additional outbreaks from insufficiently pasteurize citrus juices and concentrates.

STOP is here today to describe the qualitative side of the numbers and charts you'll b shown and the human cost of outbreaks that is not typically measured. To epidemiologis and doctors at the CDC and to investigators at FDA, we are numbers and percentages for purposes of reporting. Yet officials can't begin to count the people whose doctors sim don't culture diarrheal stool, and they won't follow up on miscarriages and stillbirth They don't ask about children turned away from emergency rooms. And, importantly for y as you weigh risk factors, they do not begin to measure the long-term cost to people w kidney failure, chronic bowel problems, diabetes, or reactive arthritis that can resul from foodborne illnesses.

Juice victims are not just statistics. We have faces. Here are two.

This is Brandi and Tenner Ulray. Brandi was eight weeks pregnant with her second child when she and her 2-year-old son went out to breakfast with her father. It was to be a joyful occasion. Brandi planned to tell her father for the first time about the pregna and they would talk about her college commencement just nine days away. She had been attending night classes for three years to finish her degree. They were expecting 15 friends and relatives to come for the celebration. At the restaurant Brandi ordered or juice for Tenner. As the meal unfolded and she told her father the good news, she took sips from Tenner's juice.

The next night Tenner had diarrhea and abdominal cramping. His parents were awakened a 3:00 a.m. to the sound of Tenner screaming. He had thrown up all over his bed and poop in his pants and was trying to make it to the bathroom. By the next day, Brandi was al sick with diarrhea, abdominal cramping, nausea, and headache. For the next four days, held Tenner as he screamed and cried in between trips to the bathroom. When an attack coming on, he would clutch his tummy and fall to the floor while crying, "Mommy, owee, owee, owee."

During that time she called the triage line four times in two hours, but they kept telling her that he hadn't been sick long enough.

On the fourth day of Tenner's illness, the doctor said it was just likely a tummy bug. Though the doctor noted blood in his stool, she told Brandi that if Tenner still felt

in three days, the doctor would request a culture then. While they were at the office, Tenner suffered a bout of cramping, and the doctor commented, "You know, little kids just don't understand what a tummy ache is, so it's scary for them. That's why he's screaming." A teenager suffering from this same outbreak was put on morphine for the pain.

Brandi told the doctor that she was pregnant and asked if the illness could harm the baby. She was assured that the flu would not harm the fetus.

Over the next several days, Tenner began to get better, but Brandi's condition deteriorated. On the eighth day, she vomited until she was dry-heaving and then collap on the floor of the bathroom. Her head ached so badly that she could barely move. Her stomach churned and gurgled. Her husband managed to get her into bed. She slept for fo hours, and when she woke up, she had begun to bleed vaginally.

On the tenth day, her graduation day, she woke up with contractions and diarrhea. She was bleeding heavily by this time and was in a lot of pain. Brandi's mother-in-law mentioned that she had seen news about the Sun Orchard outbreak and that the symptoms described matched what Tenner and Brandi had been going through. Brandi called the restaurant. The manager there assured her that they had never carried the tainted juic all of their juice had been pasteurized, but he did say that just out of courtesy they pulled all their juice from the shelves.

Several weeks later, the family would have genetic fingerprint from Tenner's positive culture that pointed right back to the restaurant. That same restaurant is even today serving unpasteurized juice that is noted as fresh squeezed on the menu.

Brandi never made it to commencement. Instead, she was rushed to the ER. Diagnosis: complete miscarriage.

In addition to Brandi and Tenner, almost 500 other identified victims and countless others that were unidentified were affected by the Sun Orchard fiasco, victims who ran in age from 2 to 88. One was an Alzheimer's patient in an institution. And Sun Orchard juice was implicated in the death of a senior citizen. You won't hear his name today because Sun Orchard has settled with his family. This man, a father, was taken out to Father's Day meal and served unpasteurized orange juice. I think he deserves a moment silence because three years have gone by since the 1996 juice meetings--three years of delay, three years of illnesses and death, three years of acting as if we haven't had enough science when a solution was available three years ago.

[Pause.]

MS. GIRAND: Let's talk about science and risk assessment for a moment. STOP has been skeptical about the strength of analysis behind the recommendation of a 5-log reductio sufficient to render juice safe. We have repeatedly asked for data supporting it. A nu of assumptions were made by this Committee, assumptions that in the last three years s to have proven less and less valid. Here are seven key points that we believe refute t validity of 5 logs. We have data for these, and in the interest of time, we will distribute it later today.

If you have any doubt in your minds after three years as to whether 5 is the right number or not, then you owe it to consumers to adopt more conservative recommendations But let's put this question aside for the moment and talk about a series of issues tha are being raised today.

In developing the juice performance standard, the Committee treated the issue of organism reduction as a black box. Fruit went in, never mind its condition, temperatur or how much the pathogen load was on it. Juice came out at the other end.

By not recommending any specific proven technology by which this standard could be achieved, you left FDA and industry the enormous task of defining what could and could

take place inside the black box. Because this Committee's recommendation was so unspecific, the industry has been developing ways to wash the fruit in Florida and jui it at a grocery store seven states away and claim that it has been treated for safety purposes as if it were heat pasteurized.

Small operations, juice bars, and smoothie restaurants were declared exempt as if they had some unique way of keeping their juice safer, even though they played key roles in Sun Orchard and Livesey (ph) Orchard outbreaks. The result has been that consumers hav been used as guinea pigs.

As you review the latest data over the next few days, we urge you to consider the following: Your charge is not to defend average consumers against the average juice producer; rather, you must produce recommendations that protect all consumers from producers that, through ignorance or negligence or economics, produce significantly contaminated juice.

To assume that these factors are trivial matters of implementation is a luxury. Industry and consumers need a straightforward solution that even the smallest producer implement. Today in this room we need applied science, not just a gadonkan (?) experim

When this group addresses risk assessment over the next two days, STOP urges that you add a safety margin that takes into account the way some members of this industry have responded to the need for safety. Food safety is only as good as management's commitme to it.

Mark Isaacs, president of Sun Orchard and former president of the American Fresh Juice Council, at the November Florida meetings last year publicly stated that industry had most to leave from an outbreak when consumers pay with their lives. Many members of th unpasteurized juice industry want to produce safer juice. You must ensure that those t are not committed to safe juice produce safe juice as well.

STOP believes the answer for juice today is a single-kill step prior to packaging, not a multiple-step Rube Goldberg contraption. With heat pasteurization, government and industry have settled on a safety standard for milk that has served consumers well for decades. Based on the juice outbreaks visited on consumers in the pursuit of more scie STOP has become convinced that in the United States today all juice should be heat pasteurized. Rather than start with a minimal standard and keep increasing it as outbr occur, we would urge this Committee to adopt a higher standard.

The new juice performance standard must take into account that there is no mandatory minimum level of sanitation for fruit as an input to juice and that you in FDA are una to guarantee it. The new performance standard must take into account a high level of pathogen contamination coming in on a large quantity of fruit growing higher under unrefrigerated conditions, potentially spreading and uptaking pathogens water, arrivin a juice that is less acid than expected. It should recognize that the juice will be produced at small orchards, large plants, restaurants, juice bars, and grocery stores.

If you intend to continue supporting multiple-reduction steps, then you must increase the standard to take into account the risk of failure inherent at and between each ste

Ladies and gentlemen, you decide. Either you are creating a safety net or it is just a collection of loopholes. If there is only one proven technology that achieves this performance standard today, you should recommend it.

I'd like to close on this note. This year, my daughter is in the first grade, and she was asked to write about what she would like to do when she grows up. She doesn't real know what she wants to do, so she wrote this. It reads: "I like to save people from apple juice and get awards."

You know, my prayer is that when my daughter grows up, we will not still be trying to save people from unpasteurized juice. Three years is much too long when the technology

solve the problem has been around for 100 years. The time has come to use it.

Thank you very much.

MS. OLIVER: Thanks, Laurie.

Our next speaker will put the focus on the meeting. And that's Dr. Terry Troxell, the director of our Office of Plant and Dairy Foods and Beverages at FDA Center for Food Safety.

DR. TROXELL: As Dr. Kvenberg outlined earlier, in December 1996, the Advisory Committe made several recommendations to FDA regarding--

MS. OLIVER: Terry, could you speak into the mike, please.

DR. TROXELL: Sorry.

In December 1996, the Advisory Committee made several recommendations to FDA regarding juice safety. After discussing data presented at the public meeting on juice safety, t Advisory Committee concluded that the history of public health problems associated wit fresh juices indicated a need for active safety interventions, and for some fruit; for example, citrus, the need for intervention may be limited to surface treatment, but fo others; for example, apples, additional interventions may be required.

In addition, the Advisory Committee recommended the use of safety performance criteria instead of mandating the use of a specific intervention technology such as thermal processing. The committee recommended that an adequate level of safety could be achiev by requiring interventions that have been validated to achieve a 5-log reduction in th target pathogen.

The Advisory Committee also recommended that HACCP form the general framework for the safety interventions. FDA subsequently developed and published, in April 1998, a propo rule to require that juice be processed under a HACCP system. FDA proposed to require juice processors include in their HACCP plans control measures that will produce at le a 5-log reduction in the pertinent pathogen.

Consistent with the committee's recommendations, the Agency did not propose a specific intervention technology; for example, pasteurization, but instead proposed a flexible 5-log performance standard that theoretically could be met through cumulative steps an at least for some fruit, for example, oranges, potentially through surface treatments.

In the preamble is a proposed HACCP rule. FDA stated that pathogens are not reasonably likely to be present in the interior of sound, whole oranges or other citrus fruits an further, that the acidic nature of citrus fruits may inactivate any pathogens that may present.

In the proposal, FDA further noted that steps such as culling, washing, brushing and sanitizing the surface of fruit, followed by extraction that minimized contact with th peel, could be used cumulatively to attain the 5-log reduction, as long as processors could validate the reduction under their HACCP systems.

Comments to the proposed rule have challenged FDA in two areas related to the performance standards and its application.

First, comments, as well as new information available to FDA, have questioned the assumption that pathogens are not likely to be found in the interior of citrus fruit a have further suggested that surface treatment of fruit alone may not be adequate to en the safety of juice. In addition, FDA has undertaken research that suggests that, unde certain conditions, pathogens could be internalized into citrus fruit and could surviv and grow once inside the fruit.

Second, comments have requested that the Agency identify a starting point for the 5-lo reduction. Therefore, FDA is asking the Advisory Committee to provide recommendations regarding these two areas of concern to ensure the safety of juice.

The first area of concern, the adequacy of surface treatments, is limited to citrus fruit only. At the time of the proposal, the Agency did not consider surface treatment be adequate for any commodity, other than possibly citrus fruits. The Agency received comments questioning the assumption in the proposed rule that pathogens are unlikely t found in the interior of citrus fruit.

As a result of these comments, the Agency conducted research to address the question o pathogen internalization in citrus fruit. This research will be described in more deta by Dr. Arthur Miller later this morning. As a result of comments challenging the Agenc assumption about the likelihood that pathogens could be found in the interior of intac citrus and the results of research undertaken by FDA to address the question of internalization of pathogens in citrus fruit, FDA has the following questions about internalization and survival of pathogens:

Is it valid to assume that there is no internalization of pathogens in citrus fruits?

If internalization of pathogens in the citrus fruit is theoretically possible, is such internalization likely to result in a public health risk?

If internalization does occur and it results in a public health risk, are there techniques to ensure that internalization of pathogens does not occur? What are they?

A second area of concern involves the application and measurement of the 5-log reduction. As mentioned previously, comments requested that FDA define a starting poin for the 5-log reduction for the processing of all juice. The committee's original recommendation did not address this. In addition, comments have expressed concern that 5-log requirement may be inadequate for particularly dirty incoming fruit.

The Agency has the following questions about the application and measurement of the 5-log reduction standard. At what point in the production process should a processor b measurement to measure attainment of the 5-log reduction? For example, should fruit be cleaned and culled before measurement of the 5-log reduction has begun?

Comments have also expressed concern about the use of cumulative steps to attain the performance standard that would allow for potential cross-contamination of juice betwe steps. Comments maintain, and the Agency has concern, that although these steps could theoretically be combined to achieve a 5-log reduction, in actuality, there would be t many points for potential cross-contamination for a processor to consistently ensure t safety of the juice. Therefore, the Agency asks:

Are there limits within which the 5-log reduction must be accomplished?

Would using cumulative steps that are separated in time and location impact a processors ability to achieve and deliver a 5-log reduction?

Can the safety achieved by the 5-log reduction be maintained consistently if a processor does not package product immediately after attaining the 5-log reduction?

Some examples of the aforementioned situations include:

One, operations that perform certain steps on the exterior of the fruit at one locatio resulting in a portion of the cumulative 5-log reduction and then transport this fruit another location, where the remainder of the cumulative 5-log reduction is achieved;

Two, firms that extract juice at one facility and then transport it via tanker, large drums or totes to another facility for packaging; or

Three, firms that hold juice overnight or longer for mingling with other juices to attain desired quality attributes in the final product.

The committee has been provided copies of the documents, the literature review and research papers related to the question of the adequacy of the surface treatments for citrus fruits. The speakers following me will provide more detailed information for yo consideration in making recommendations on all of these questions.

Thank you.

MS. OLIVER: Thanks, Terry.

What I'd like to do is just remind the committee that in your package you have the questions that were presented to NACMCF, the questions that FDA would like answered. Y also have in your packet the NACMCF recommendations to FDA on the safety of juices fro the previous meetings that was referred to by Dr. Kvenberg. If you want clarification, refer to that.

The next thing that we have on the agenda is questions of clarification. And once again, I remind everybody this is for the committee members first to ask questions of of the previous presenters to clarify any of the points that were presented. And those are not at the table that were presenting, I would ask those to come forward to the fr of the room to respond to any questions that the committee might have.

And for the committee members, once again, I'd ask you to introduce yourselves first s that it will help with the transcription.

Thank you.

Are there any questions from the committee at all on clarification of any of the comments or presentations by any of this morning's presenters?

Bill?

MR. SPERBER: Yes, I'm Bill Sperber with Cargill. I have several questions for Mr. Martinelli from Orchid Island.

If possible, I'd like to learn a little more about your operations. Was the treatment of the incoming fruit juice--you mentioned several times that you have a high-pressure sanitizer spray. What type of sanitizer and what concentration are you using?

MR. MARTINELLI: The high-pressure spray that I was talking about on the incoming fruit was the sanitizer that we use in that spray was CS-100 from Chem Systems. The concentration is, it's higher than--I don't know exactly what the concentration is, bu know it's higher than the recommended concentration by the manufacturer, sir.

MR. SPERBER: I don't know what CS-1 is. Do you know that chemical?

MR. MARTINELLI: Thank you very much for the question. I'm the executive vice president at Orchid Island Juice Company, sir. We invite people to come to our facility where someone can further explain all of the intricacies of all of the chemicals that we use our facility. We offer that openly to everyone.

MR. SPERBER: Sure.

Then, my other question has to do with cleaning and sanitation of your extraction and further processing equipment. And perhaps you don't know the answer to this either, bu believe it's more important than the fruit treatment.

You said that extraction equipment, et cetera, is CIP'ed at the end of each day,

sanitized, and then rinsed with potable water, and it's ready for the next day's production.

MS. SEXTON: The final rinse is not potable water, is it?

MR. SPERBER: That's what you said in your--

MR. MARTINELLI: No, it's a sanitized--it's injected with CS-106, and it's potable wate injected with a sanitizer, but that's not what's used in our CIP, sir. Our CIP is a caustic flush, and then it's a sanitizing rinse.

MS. SEXTON: Are you with a pasteurizing company because--

MR. SPERBER: Cargill.

MR. SEXTON: Because we also hand break down, if you want to go into the cleansing breakdown, we break down our extractors by hand every single day.

MR. SPERBER: No, my major concern was that you would be rinsing equipment with potable water, letting it sit until the next day and then starting up production, and that wou be a poor practice.

MR. MARTINELLI: We don't rinse any of our equipment with just straight potable city water. We inject a sanitizer into it, and it's CS-106 from Chem Systems.

MR. SPERBER: Okay.

MS. SEXTON: Because we know the 5-log reduction we do realize was brought on by the subcommittee that it was stated that that was a water, a drinking water, regulation. S know that there are hazards to drinking water.

MR. SPERBER: Right. Okay. Thank you.

MS. OLIVER: Alison?

MS. O'BRIEN: I have a question for Laurie.

MS. OLIVER: Can you identify, too, please.

MS. O'BRIEN: I'm Alison O'Brien, Uniformed Services University of the Health Sciences. Thank you.

Would you please review how many outbreaks there have been--that the slide did not sho on your computerized graph--how many outbreaks there have been since the 1996 meeting how many, to your knowledge, were due to unpasteurized orange juice.

MS. GIRAND: There have been, in the U.S., two unpasteurized juice-related--it's an outbreak and a recall. Both were by Sun Orchard, in particular. There was also an outb in Adelaide, Australia, from unpasteurized orange juice that affected more than 400 people.

MS. O'BRIEN: Thank you.

MS. OLIVER: Mike Doyle?

MR. DOYLE: Mike Doyle, University of Georgia. I have a question for Mr. Martinelli.

Do you routinely test your juice for salmonella?

MR. MARTINELLI: Yes, we do, sir.

MR. DOYLE: And what procedure do you use?

MR. MARTINELLI: We use a Tritech Laboratory procedure, and it is consistent with--when the CDC came out with their testing, after the first Sun Orchard outbreak, we sent tha testing immediately to the Tritech Laboratory, and it is consistent with the CDC testi the way of testing for salmonella, and E. coli, and other pathogens that might be in f juice.

MS. OLIVER: Larry?

DR. BEUCHAL: Larry Beuchal, University of Georgia.

I would ask, also, John, do you test only the juice or do you also test the oranges fo microbiological profiles?

MR. MARTINELLI: We test our juice, sir.

DR. BEUCHAL: What is the, over the period of a year, say, the range in temperatures of the juice, rather the orange or the oranges, and also the water that is used to rinse sanitize the oranges?

MR. MARTINELLI: The fruit temperature is always ambient temperature. It's water the outside environment temperature is, and the water is always ambient temperature tap wa that we use. We don't use any heated water or anything like that. We use strictly sanitized water.

DR. BEUCHAL: What is ambient temperature in your facility, in your area?

MR. MARTINELLI: I would suggest, sir--I'm not an expert on this--but I would think tha tap water would be somewhere around 70 to 80 degrees, and fruit temperature would be anywhere from, internal temperature would probably be 40 degrees to 75 degrees/80 degr

DR. BEUCHAL: Thank you. Do you have an indication of pH range of the various cultivars the various varieties of oranges that you would use in your product?

MR. MARTINELLI: I do not. I think that I'm sure there's data out there in reference to that, sir, and I know we have logged pH ranges of our fruit during the extraction proc We don't do that any more since we found that it wasn't critical to the quality of the product.

DR. BEUCHAL: And going back to the question raised by Dr. Sperber, the CS-100, is it?

MR. MARTINELLI: Yes, sir.

DR. BEUCHAL: Would there be anybody here that could tell us what the composition of that sanitizer is.

MR. MARTINELLI: This is Dr. Dan King, from the Fresh Juice Company.

DR. KING: Thank you. I just made a quick call to verify some numbers. The phosphoric acid base wash that they use at Orchid Island is about 100 parts per million minimum. point of comparison, at Fresh Juice, we use a citric acid wash at about 175 parts per million minimum. In addition, there are chlorine components involved; for instance, chlorine dioxide added as a commercial form oxine, which is at 15 parts per million minimum, which is the equivalent of at least 200 parts per million chlorine.

DR. BEUCHAL: Are all of these in this CS-100 Chem--

DR. KING: No, the CS-100 is the phosphoric acid.

DR. BEUCHAL: All right. But then the citric acid is used--

DR. KING: It's used in place of it. It's used particularly with organic citrus processing, organically grown.

DR. BEUCHAL: And there is no surfactant, apparently, in any of these.

DR. KING: No.

DR. BEUCHAL: Thank you.

MS. OLIVER: Dane?

DR. BERNARD: Thank you. Dane Bernard, NFPA. I also have a question for Mary Grace or John. Hi. First, thanks for your presentation.

One of the questions that we are asked to address deals with steps that are somewhat removed in the production process. And one of those steps is presumably when juice is extracted in one location and trucked or transported to another location. Does your company receive tankers and how common is that practice in the industry, even if you don't?

MS. SEXTON: At Orchid Island Juice Company, we do not receive any tankers or provide any tankers. We do not inventory juice, also. Juice is processed, squeezed and is ship immediately. So the tanks that you see are tanks preparing it to go into the bottling system. They are not inventory tanks, and that is very, very, very important. They are not.

And, also, someone asked about lab tests. The Department of Citrus and the regulations in Florida have had us have--we were mandated that we had to use an outside lab. I bel it was between 5 and 6 years ago. So since then, and the scientists will show you the results, all juice has been tested by an outside independent lab. So this is an ongoin thing.

DR. BERNARD: Any feel for how common, though, the practice of extraction in one location for transport to another location is?

I also have a question for John regarding the--

MS. SEXTON: I just have to reiterate, I don't do tankers, I don't receive them and I don't ship them. So I'm not the expert on a tanker.

DR. BERNARD: I've heard from yourself, and from Mary Grace and from Donna that you don't immerse fruit at your operation. Are there operations that do immerse fruit?

And just for my information, could you describe your cleaning procedures for fruit.

MR. MARTINELLI: It's Dr. Bernard, right?

When the question first arose, we formed a consortium of competitive fresh-squeezed orange juice companies throughout the United States. We did a number of research information-gathering projects to find out who was immersing fresh oranges for utiliza in fresh-squeezed orange juice. None of the people in the consortium immersed fresh oranges for production into fresh orange juice, and that was pretty much the standard we recognized throughout the fresh juice industry was there is no immersion going on. that is the reason why we have--that's the reason why, sir, we feel a little anxious a this whole thing is because most of the premise of the documentation that you are goin see is based on immersion of fruit, when immersion is not a common practice amongst th

conscientious fresh juice providers of the country.

MS. SEXTON: May I just restate one thing? Because I don't want to take the justice awa

of people that might possibly tanker. I don't think it's anything that's not publicly known. But the tanker that was contaminated was contaminated by Mexican water, if I understand the situation correctly. And a fresh squeezed juice processor is never, eve ever allowed to add water, first of all, to fresh squeezed products. So there was a la that was broken, first of all, and then contaminated with an outside water, out of the country. So I'm not so sure it was the tanker, rather than the processor, again.

MS. OLIVER: Earl?

MR. LONG: Earl Long, CDC.

Mr. Martinelli, could you describe briefly the extraction process for me, please.

MR. MARTINELLI: See, sir, these are my strong points. These are in my sales presentation.

[Laughter.]

MR. MARTINELLI: In an FMC extractor, what happens in an FMC extractor is the fruit is tossed into a waiting cup, and the cups interlock. During the cycle, the cups clasp do on the fruit and a mechanism is stuck into the fruit, and then the orange is collapsed around the strainer tube. At that point in time, it's released, and you can take that skin, and except for the top plug, which is about the size of nickel, and the bottom p which is about the size of a nickel, you can practically reproduce that entire skin.

Now, FMC has come up with a soft squeeze extractor, which does very, very, very little damage to the exterior of the orange as it's being squeezed. It puts some cuts in the skin, but the juice never comes in contact with the exterior of the skin of an orange during the extraction process.

MR. LONG: Is that a standard procedure in the industry?

MR. MARTINELLI: The conscientious fresh squeezed juice companies that we have in our consortium, we are all using FMC extractors.

MS. SEXTON: And on those plugs, the whole plug does not touch the juice. They have a statistic review that the razor touches a very, very, very, very small percentage of t orange that pulls that plug away from the orange for the office tube to bring the juic out. So the plug is not involved the juice. It's the razor that cuts the orange.

MS. OLIVER: Mike Jahncke, did you still have a question or was yours--

MR. JAHNCKE: My question was answered. Thank you.

MS. OLIVER: Mike Robach?

MR. ROBACH: Mike Robach, County Group Companies.

You are involved in the pilot HACCP program, and one of the questions that we have before is regarding how you determine a 5-log reduction. And I was wondering if you co go through for the committee how you determined and validated that your process was achieving at least a 5-log reduction.

MR. MARTINELLI: Thank you, sir.

When the Food and Drug Administration made a 5-log recommendation, Orchid Island Juice Company and the Fresh Juice Company, and the other conscientious fresh squeezed juice providers of the country automatically went out to achieve what the Food and Drug Administration had asked us to do.

The way we had our 5-log reduction validated was we took our entire squeezing protocol

to a test laboratory, ABC Research Laboratory, under the direction of Keith Snyder, an put together our protocol in our facility, and he went through systematically washing, scrubbing, and extracting and adding all of the chemical sanitizers and all of those o things that we have during the process of our plant that you saw today. And we came up with a validated 6.73 log reduction. I have the test data in my--I'd be more than happ provide that to you, sir.

But then the question arose: Well, how can we equate that? How do we know that Dr. Snyder and all of the processes in the protocol that he went through were exactly replicated in our plant, the 26 steps that he went through were replicated in our facility?

We got the USDA Consumer Services to come out and do an audit of the protocol that ABC Research Laboratory did in the facility. And during that audit, he went through each a every one of the 26 steps of the protocol that ABC Research Laboratory went through an documented the 26 stages were identically replicated in our facility as they were in t ABC Research Laboratory. So we don't ask anyone to assume that the Research Laboratory their job correctly. We had the USDA come in and validate that the protocol was in ord

MR. ROBACH: So USDA came in and took samples of raw fruit incoming and looked at micro numbers and load on the incoming fruit and then followed your process all of the way through the 26 steps, and then validated that you had a 5-log reduction from incoming fruit to final juice product?

MR. MARTINELLI: No. I'm sorry, sir. I must have stated that confusingly.

In the HACCP program, the first thing you do in the 5-log HACCP program, the first thing we did was we set out to validate a 5-log process. In the validation of the 5-lo process, we recognized that there were critical areas where, if this didn't happen, th your 5-log would be interrupted, if this didn't happen, and those are what we call our critical control points.

In a HACCP program, the reason why a HACCP program is a HACCP program is because, in the validation studies at ABC Research Laboratory, if, in fact, one of these steps mis then you wouldn't have your 5-log. At the ABC Research Laboratory, we validated our st we implemented a HACCP program to make perfectly sure that the steps of that study wer routinely followed on a day-to-day basis and, subsequently, the information that we go from ABC Research Laboratory was supported by our HACCP program.

MS. SEXTON: And I just wanted to verify, we did not use--

MS. OLIVER: Mary Grace, if you could speak into the microphone. I'm sorry. And I know-

MS. SEXTON: And I want to reemphasize, we did not use a surrogate. We used what you asked us to use; E. coli 0157H7. We did not, you know, pansy around. We used exactly w you wanted to kill.

MS. OLIVER: If we could restrict, for now, but we will open it up for other questions later, if we could restrict it to the presenters.

DR. STROBOS: I just wanted to address the 5-log question because we worked together on this. MR. MARTINELLI: This is Dr. Jur Strobos. He was one that was instrumental in bringing together the consortium of fresh squeeze orange juice companies that have validated their 5-log and do make a fresh-squeezed product.

DR. STROBOS: I just wanted to answer the specific question about several different companies have done it several different ways. In the docket, in November 19th, we submitted basically 40 copies of not only the Florida regulations, which actually addr many of your questions. Exactly what the sanitizers are, for instance, is specified in those regulations.

Additionally, in that docket, also we submitted experimental data from 5-log reductions. Different companies did it different ways. That data on how different companies had achieved it was the subject of seminars in Florida and California. Transcripts of those were also submitted to the docket.

Just to briefly go over it, however, Orchid Island did studies with regard to E. coli. We, at the Fresh Juice Company, using a surrogate, we did exactly what you had describ in other words, tested incoming fruit for the surrogate, validated the surrogate reduc through the process to about a 6-log reduction to the final juice.

MS. OLIVER: Next, John, you had your hand up quite a few times. Did you have your question answered?

MR. KOBAYASHI: Yes.

MS. OLIVER: Next who had their hand up, Peggy Neill?

MS. NEILL: Good. MaryGrace or John, tell us a little bit about the labeling of your juice bottles with respect to lot numbering, sell by/enjoy by date, and can you give u any profiles of what data you might have on length of time from production to consumpt

MR. MARTINELLI: Ma'am, a lot of what you're asking was covered--was made in a recommendation by the Department of Citrus about 4 or 5 years ago, and the Department Citrus wanted us to have the ability to trace back to the grove each jug of fresh oran juice that we produced. Our coding on our juice, not only tells us what tank the juice came from, it tells us who the person was who handled the jugs that put in on the line tells us who was in operation at the bottler at the time, and it does tell us--it puts 17-day code on it.

Now, the 17-day code is mandated by the Florida Department of Citrus, and that is a quality requirement mandated by the Florida Department of Citrus, and we're not allowe go over that 17-day code.

MS. OLIVER: Okay. Scott Severin.

MR. MARTINELLI: Ma'am, was that--

MS. NEILL: Sort of. I remember your presentation in '96, and I remember some of the slides, and as I recall, the coding also included what essentially would be your produ with something like only one day's--a lot was one day's production or a segment of a d and the you had further subsets from there, so you could tell who had handled it, what line, what tank, et cetera, with the idea that that is information or greatest relevan for trace back, occasionally for trace forward.

MR. MARTINELLI: Right.

MS. NEILL: Can you elucidate on a trace forward? In other words, can you--I realize some of this might be market data, but can you tell us something about what you might known on estimated length of time from production to consumption?

MS. SEXTON: Our customers, when you have--we're very proud, we have the best customers in the world. And they are trained, and we work very closely with them that they don't inventory juice. Customers as far as Boston will get two-time a week delivery, so they rotate that juice every two to three days, and then they get their new shipment in. We train our customers to keep it so tight, but not everyone has to do this. If they go s we fly the juice in, because we like fresh. But we do have a 17-day shelf life that ha been mandated.

MR. MARTINELLI: The time from production to consumption, ma'am, in a wholesale application such as a food service distributor, I would say that they're probably goin

be getting the juice into the restaurant's hands within 4 to 5 days after production. restaurant will probably consume that product within two days, two or three days.

In retail applications where we deliver directly to a distribution unit, the distribution unit will get the juice, in most situations, the day after, so it will be days into the distribution unit. They'll get it out in 3 days, so it will be on the sh in 5. A lot of our retailers, because of the regularity of our deliveries and the fact that we ship the juice as soon as we squeeze it, have actually had us change the code 14-day code, so they're pulling the juice off the shelf even when the customer still c consume the juice for 3 more days, or they could have it on the shelf for 3 more days.

MS. NEILL: So my last point would be that you would estimate that something that's a small minority of the product--I don't know what it is, maybe 10 percent of the product--is actually consumed, let's say, in the latter one-third of your 17-day windo You presumably have something in which the majority, over 50 or 60 percent, is going t consumed probably within 8 days, within half of your 17-day window?

MR. MARTINELLI: Yes, ma'am. And I think that's a very good estimate. I think there wil be some that will be shorter and there will be some that will be longer. We like distributing into like home delivery dairies. They're a very good application for us, because they get the juice in, and the next day it gets delivered to the consumer, and consumer is drinking the juice in 3 to 4 days. So the more direct the supply line, the better it is for the consumer and the distributor also.

MS. NEILL: Okay, Scott?

MR. SEVERIN: Scott Severin, Office of Surgeon General.

John, you were talking about your HACCP plan, and I believe you said your second critical control point had to do with harvest delivery, harvester verification on drop specifically?

MR. MARTINELLI: Right.

MR. SEVERIN: And you said that if they have drops, that they whole load is rejected. How do you verify that?

MR. MARTINELLI: Thank you. Good question. The second critical control point in our HACCP program, sir, is our food acceptability. What we do is in order to test a sample our truck, we go and visually observe the truck. In a stem scar scenario--and we'll be hearing a lot about stem scars--in a stem scar scenario, when the fruit is picked off true you'll see a fresh stem scar. It's almost like cutting the stem of a rose. You ca see a fresh one. After a certain number of hours, that stem scar will start to keel ov and almost become callous. The fruit will start to wilt and in some scenarios it will brown and even have a little sand on it. If we see any of that in a truck, we know tha there was no integrity put into the harvesting of that product, and we reject that tra immediately because our growers know that there's--our harvesters know there's plenty places to take that kind of fruit, but Orchid Island Juice Company is not one of them.

MR. SEVERIN: Well, what type of other sources or delivery sites would they use that type of fruit for?

MR. MARTINELLI: Something, sir, that has--something, sir, that can really impact--

MS. SEXTON: A pasteurized company has a tolerance for that.

MR. MARTINELLI: Pasteurized companies have more of a tolerance for using dropped fruit and unwholesome fruit than fresh squeezed juice companies do. And, sir, one of the rea why that is, is because, as you saw in Florida in the Florida model of inspection, we the Florida Department of Agriculture in our facility every single day, and there's a random sampler in line with our production line. And what it does, is it takes a piece

fruit randomly from the production line, and then sample it into the Department of Agriculture office.

The Department of Agriculture has set a zero tolerance for fresh-squeezed orange juice as far as unwholesome or decayed fruit. And we think the Department of Agriculture is serious about that, and that's why we have, in a facility that is one-third the size o Odwalla's, we had--I think Odwalla, during their outbreak, sir, had three graders on t line, and we have 12, and we're one-third the size of Odwalla. So we--and it's all bec of MaryGrace's inspiration. We try and make a product that is safe enough to our child because, you know, I have to go home and look at my child every day too, and I don't w any kind of incident to happen there. So food acceptability is the second part of our critical control point.

MR. SEVERIN: Thank you.

MR. MARTINELLI: Thank you, sir.

MS. OLIVER: John Kvenberg.

DR. KVENBERG: Thank you.

I have a follow-up question for John.

MS. OLIVER: John, if you could get closer to the microphone.

DR. KVENBERG: I'm sorry. For John Martinelli. It's a follow-up question to what Dr. Sperber asked earlier relative to the sanitizers that are in use. And I realize the question was out of the context of your presentation this morning, so if you don't hav the answer now, maybe you could answer it later. But is it not true in the final sanit application, you're using a parasitic acid--

MR. MARTINELLI: Absolutely.

DR. KVENBERG: Brand new Tsunami?

MR. MARTINELLI: Tsunami, parasitic acid.

DR. KVENBERG: Yeah, that's my memory. Thank you for sharing that because that is much different then phosphoric acid.

MR. MARTINELLI: And in the original testing at ABC Research Laboratory, we did not us parasitic acid as our final sanitization step, we used something else. But the Food an Drug Administration, on the Food and Drug Administration's recommendation, we checked that product--and I forget what product that was. I think it was--I don't know what it was. But we changed it because it was not approved for raw agricultural commodities, t used in the sanitization of the exterior of a raw agricultural commodity. We changed t parasitic acid, and parasitic acid has done an excellent job in the exterior sanitatio the fruit.

MS. SEXTON: We revalidate every time we change something.

MS. OLIVER: That's what I wanted to know.

MR. MARTINELLI: Is that the question you were going to ask?

MS. OLIVER: That's what I was just going to ask, if they revalidated--

MR. MARTINELLI: And Dr. Nagle was going to talk about the revalidation. If any process in our facility is changed, if we--as a matter of fact, if we wanted to reduce the num of graders we had on a line, that would be a critical control point. It would take a revision in our HACCP plan, and it would have to be documented as a revision, and we w

taught that by the Food and Drug Administration.

MS. SEXTON: And then it would be reverified by the outside lab also.

MS. OLIVER: Phil Sveum?

MR. SVEUM: Phil Sveum, Campbell Soup Company.

I have a question about your process control program. You mentioned at length that you have these alarms for the sanitizers. We talked about that. You talked about finished product testing. Do you have any environmental control program where you're monitoring target organisms or a pathogen during the process of after sanitation, so we have a le if you ever do get challenged by that organism?

MR. MARTINELLI: Good question, sir.

Not on-site, and the reason being is because when we were trained on our HACCP program a true, pure HACCP program puts into place critical control points where the juice or fruit can be contaminated, and we would lose our 5-log validation. In a HACCP program, monitor our critical control points regularly, and sometimes with visual and audio ala We also give the graders the capability to shut the entire facility down if in fact th dilution of our sanitizer goes out of specifications, or the volume of fruit is incorr We do all these things because the way we were trained, HACCP is a process by which yo monitor your critical control points once they're in place and once they've been validated, and as long as those critical control points are within the specifications, are achieving the safety level that you set out to achieve.

MR. SVEUM: As a follow-up then, you don't have any existing in-process microbiological verification program of these controls? You validated it and then that's it; you're ju going by the alarms?

MR. MARTINELLI: In our--

MS. SEXTON: Does he understand we have the pre-sanitizer?

MR. MARTINELLI: Sir, you don't understand. Our first critical control point was bioluminescence testing of our fruit surfaces and our juice surfaces.

MR. SVEUM: Yeah, but I asked specifically if you monitor the environment for--

MR. MARTINELLI: During the process.

MR. SVEUM: --a pathogen at any time or a target organism.

MR. MARTINELLI: Can he step up? He's a doctor. I'm executive vice president in charge of operations.

MS. OLIVER: What I'd like to do is--there are like 7 more Committee members that have questions. I'd like to restrict it to hear yours on the program later, and we can ask additional questions tomorrow if we can, but--

MR. MARTINELLI: Yes, we do, sir.

MS. OLIVER: Okay. Bala?

DR. SWAMINATHAN: Bala Swaminathan, CDC.

It's been very confusing to me because you keep going back and forth between quality inspections and food safety concerns. There may be some overlap, but we are primarily to discuss food safety. And from what you have described, it seems to me that your pre is that any contaminant is present on the outside of the fruit, and so if that's taken

care of, no more problems exist. Is that correct?

MR. MARTINELLI: The data that we have collected, sir, and the fact that we have--and I don't know if this is a scientific test or not--but we've done over 1 billion pieces o fruit, and we have not--through outside independent laboratory testing over the last 5 years, we have not had any internalization or we've not had any pathogens in our produ I would say my answer to that would be yes.

MS. SEXTON: But you have to clarify that we do a visual inspection and touch every piece of fruit, you have to understand, so what you're stating is that once we wash it we're finished, and that's not correct. You have manual people inspecting visually eve single piece of fruit.

DR. SWAMINATHAN: Visually I couldn't detect E. coli 0157 or salmonella on fruit; can you?

MS. SEXTON: No, but your 5-log reduction's already killed it.

MR. MARTINELLI: That's a good question, sir. When the Food and Drug Administration initially put forth the 5-log safety standard, we set out to prove that it could happe citrus juice. It was on the exterior of the fruit because internalization has never be proven in a normal setting.

We did. We set out, and through our protocol we achieved a 6.73-log reduction on E. coli 0157:H7. No, sir, we can't see--we cannot see E. coli 0157:H7, but I don't think can see listeria on fish either, but the HACCP program in the fish industry has worked very, very well to stop that from happening.

DR. SWAMINATHAN: My next question: are the details of this testing done by the outside laboratory available for the Committee? Could we see what are the tests that are being done, or is the product being tested for indicator organisms? Do you have specific act levels if the testing company finds something positive in your product? And finally, h the company ever found pathogens, whether it's listeria or E. coli 0157, or salmonella your products since the testing began? And my last question is: What are your specific objections to pasteurization? Thank you.

MR. MARTINELLI: Has Tritech Laboratories ever found listeria, E. coli 0157:H7 or salmonella in our product? No, they have not. In the last 5 years the consortium--I ca give you the data of the consortium, sir. The consortium that we put together of competitive fresh-squeezed orange juice companies has squeezed, in the last 5 years, 2 billion oranges. We've done 17,000, over 17,500 microbial tests in laboratories, and h not had a salmonella or E. coli or listeria hit in our test results.

Our objection to pasteurization, sir?

MS. SEXTON: May I answer that?

MR. MARTINELLI: Our objection to pasteurization?

MS. SEXTON: Yes. The objection to pasteurization is that people think that's a cure-al and it's safe, and that that's the end road. They have many recalls in pasteurized products, many, more than fresh-squeezed juice will ever have. For the consumer, all y want to do is blanket the problem, and my children are too important to say pasteuriza is safe for everything, because we know it's not. We know on a child's menu hamburgers kill them, hot dogs kill them, cereal has salmonella in it. Well, you can't simplify t fact: food processors have to be responsible, whether they heat it, whether they bake or whether they cook it.

MS. OLIVER: Okay. Next I'm going to call on Dr. Larry Beuchat. We have about a minute for questions before our break, and Dr. Beuchat will not be here tomorrow. The--I beli our presenters will also be here tomorrow, so that when the Committee is asking questi

for clarification tomorrow, you will be available also, since there are a number of questions unanswered, correct?

MR. MARTINELLI: Yes. And I'll also have the documentation of our study tomorrow if that's okay, Doctor?

MS. OLIVER: Dr. Beuchat?

MS. OLIVER: Thank you.

Actually, Dr. Swaminathan was touching upon this question. Do you know the procedure, detailed procedure for applying this surrogate E. coli, I assume, to the orange? Do yo know the details on that procedure?

MR. MARTINELLI: Well, first, sir, it wasn't a surrogate. It was the actual pathogen in the ABC Research Laboratory. And do I know the application?

DR. BEUCHAT: Yes. What was the procedure? Can you help us?

MS. SEXTON: We have the whole protocol.

MR. MARTINELLI: I have a copy of the protocol.

DR. BEUCHAT: That will be helpful.

MR. MARTINELLI: If that's okay. I mean, sir, I'm not a scientist by any stretch of the imagination. I don't even think I took many science classes.

MS. OLIVER: Okay. We're going to take a break now, but I know a number of the Committe members still had questions. And our presenters will be here tomorrow, so if there are additional questions that you have for them, they'll be available then, or if we have later in the day, we'll revisit this. Thank you very much. We'll convene at 9:50.

[Break from 9:35 to 9:47.]

MS. OLIVER: I just want to make a couple of announcements based on some questions I go from the Committee.

If someone could close the door or ask people to come in, please? Thank you.

A number of questions arose about the Florida regulations and Jur Strobos told me that he will be addressing that during his talk.

Some other questions arose surrounding the Orchid Island and their procedures, and Orchid Island has agreed to supply their validation data, and I'll be talking to them later to see if they can answer more specifically some of the questions that were responded to this morning--or after this morning so they can have it for the Committee tomorrow, so I will do that, and they will be here tomorrow.

And trying to move on and get us back on track, the next speaker is Dr. Mary Lu Arpaia from--a post harvest plant physiologist from the University of California at Riverside

and she is going to speak top us on factors affecting the integrity of citrus fruit. D Arpaia?

DR. ARPAIA: Thank you. Can you hear me? Good morning.

As I was introduced, I'm Mary Lu Arpaia. I work for the University of California. I'm cooperative extension specialist in the Department of Botany and Plant Sciences at the Riverside Campus. I work with citrus and avocados predominantly, and I work with both and post-harvesting handling systems for those two commodities.

Today, what I thought I would do in the 30 minutes that are allotted to me, is to briefly review how fresh fruit are handled in California. Approximately 80 percent or greater of all the citrus that is grown in California is sold as fresh product, and th remaining is sent to processed products.

So an overview for the presentation I'm going to give you today, I want to talk very briefly then about the California citrus industry, to give you a background on why we things the way we do. I'm going to give you a very brief overview about post-harvest biology of citrus.

The underlying premises in which we have structured how we handle the fruit is due to disease susceptibility to plant pathogens, so I want to cover the plant pathogen management for fresh marketing of citrus. I'll give you some examples of some grade defects, and then I'll quickly review handling procedures in a packing house setting.

So in California we grow citrus, it's grown throughout the state in a wide variety of environments from Southern California near the Mexico border up through the Sacramento Valley north of Sacramento by about 50, 60 miles. So they're grown in diverse climates under different conditions.

Approximately 75 percent of all the citrus grown in California are oranges. Navel oranges account for approximately 50 percent of the entire state's acreage, Valencia oranges about a quarter, about 25 percent, lemons accounts for about 18 percent of the total acreage, with grapefruit about 5 percent.

Citrus is very important to the economy of California. You can see here in the 350--this is actually agricultural commodity listed by the California Department of Fo and Agriculture. Oranges ranked in 1997 as the 11th most important commodity, lemons number 20, and grapefruit number 56. So you can see that in terms of the big picture, California citrus is very important to the economy of the state.

We harvest fruit year-round, I just want to point out here real quick. Navel oranges are harvested from about mid October through the month of about June; Valencia oranges starting in the Cochilla [ph.] Valley are picked in February, and harvest of Valencia oranges extends then into the fall months. So essentially we have citrus harvested, an oranges in particular, 12 months of the year.

So moving on then to post-harvest biology, plant pathology and disease management. The two underlying principles from a citrus perspective in terms of post-harvest handling that the fruit are non-climacteric. This is a characterization of fruits that--in the post-harvest arena--into either climacteric fruit such as apples, kiwi fruit, pears, tomatoes are climacteric fruits. These are fruits that typically will undergo distinct ripening changes either on the tree or after harvest. So a great example would be the tomato turning from green to red during the ripening process, or a banana.

Conversely, products such as citrus and grapes are considered non-climacteric. These fruit basically is what you harvest off the tree is what you get. They do not show a increase in respiratory activity following harvest, and their response to ethylene var from climacteric fruits.

The other key characteristic of citrus as a group is that they are chilling-sensitive. This means that we are limited by the storage temperatures that we can hold the fruit, typically, most citrus--not all citrus, but most citrus, cannot be safely stored for prolonged periods below about 35 to 40 degree Fahrenheit.

This is an example of chilling injury, low-temperature damage on navel oranges, and yo can see this occurred after six weeks of storage at 1 degree Celsius, and you can see sense of pitting occurring on the peel of the fruit. Typically we do not store our fru for that period of time or at that low of a temperature. This was an experiment we wer doing to look at potential for chilling injury.

Lemons have a unique form of chilling injury called membrane staining, in which the segment walls will become stained, and this usually occurs at temperatures below 5 degree--50 degrees Fahrenheit, but typically we do not store our green lemons at temperatures below 50 degrees.

This is just to give you an example of the respiratory response of lemons to ethylene, which illustrates the non-climacteric behavior of the fruit. Again, the fruit respirat of the fruit varies between temperatures. This is fruit held at 20 degrees Celsius , 1 degrees and 5 degrees, and so, as you would expect, the rate of respiration of the pro is decreased as you lower the temperature.

These two curves here, this curve and this curve, is the respiratory activity of the fruit when the fruit have been treated with 10 parts per million ethylene, and, again, increase in the rate of respiration is dependent upon temperature, but in a climacteri fruit, you would have the stimulation of ripening and ripening behavior and a much lar increase in the rate of respiration, but in non-climacteric fruit, this is minimized.

This bottom graph is lemons that were held at 20 degrees Celsius and given ethylene at three different times, and you can see that the response in respiration is transitory, another characteristic of a non-climacteric fruit.

By and large, though, the most limiting factor to the post-harvest life of citrus is plant pathogens and the havoc that they can wreak upon the quality of the fruit, and s can break out post-harvest citrus diseases into two categories.

One is those diseases arising from pre-harvest infection. They are listed here, and I have some slides to show you what these are. Typically, these pathogens will infect th young fruitlet on the tree, and then these infections remain quiescent until the fruit mature and harvested and put under stressful conditions.

Fortunately, for us in California, diploidea and phomposis, because of our environmental growing conditions, are not a problem. We do occasionally have problems alternaria and phytophthora, and in long-term storage of lemons, we may have problems botrytis. Anthracnose also can occur in California, but that will occur in the field, the fruit will be graded out at the packing house.

So this is an example of tear-staining on navel oranges. This is anthracnose on fall-glow mandarins, and this was provided to me by Dr. Eldan Brown from the Departmen Citrus in Florida.

Below, you see an example of botrytis. It can be a problem in long-term storage of lemons, and we do store lemons in California. I can talk about that later in the question-and-answer period if you have questions.

Phytophthroa fruit rot or brown rot can be a problem, especially when we have cold wet weather. It is caused by the spores splashing up onto the fruit during rainy weather a can cause fruit decay like this. Typically, these fruit will fall from the tree in the field, and the fruit are left on the ground and not harvested.

We can have it develop subsequent to harvest, but we use post-harvest management schemes to help control brown rot in the packing house.

Again, this is an example of phomposis and diploidea stem-end rot, both which are not serious problems for California fruit.

Alternaria can be a problem in lemons stored for prolonged periods of time, but we do control that by a pre-storage application of 2,4-D at a rate of about 250 parts per million, and this controls the abscission of the button of the fruit, and there is ver good data showing that if you maintain the vitality of the stem of the fruit, the stem or the button of the fruit, then you can control the development of alternaria stem-en

rot in storage.

Navel oranges can have a problem with alternia rot, primarily through the navel end. W have more of a problem with this when we have had very cold weather or freeze events l we had last year, but, again, the problem is not considered to be a serious problem. Specifically, you can detect this at the packing house during the grading process.

More serious for California fruit is those citrus diseases which arise from post-harvest infection, and by and large, the most important disease that we have to d with is green mold caused by Penicillium digitatum, and you can see all these pathogen occur because of fruit injuries. So the guiding light or the guiding principle of citr fruit handling, at least in California and I am sure in Florida, is to do anything possible to minimize the damage to the fruit because, if you do not minimize damage to fruit, you are going to have problems with these pathogens, and in particular, green m Penicillium digitatum.

We also have problems with sour rot occasionally. This is more of a problem on lemons that go into fruit storage, and trichoderma, again, is a problem associated with lemon storage.

This is a picture, then, of green and blue mold, and, again, green mold is the more important one for us. Blue mold is controlled very well by the fungicides that we use the packing house.

This is a slide actually I took in Chile out in the field where a grower had clipped their fruit, but had left the stems of the fruit about a quarter of an inch and then l the fruit in the bins and treated the fruit with ethylene and had all kinds of fruit decay. So this is not typical California fruit, but this can show you what will happen you wound the fruit, and these are green mold lesions developing.

Another problem why we need to control green mold, then, is you have the direct loss o a fruit, but also if the fungus begins to sporulate, you can have a spoilage problem, this causes one to have to repack the fruit. Again, we do not want to have to repack t fruit and the spores also contaminate the packing house.

This is a picture of sour rot, again, entering. This is a lemon, entering the fruit through a wound. Sour rot can be very serious because the organism exudes a peptolytic enzyme that can basically dissolve the neighboring fruit. So the organism spreads from fruit to fruit, and once it gets going, it really does not need wounds. It is usually a problem in long-term lemon storage when we have had very wet weather.

This is trichoderma and rot. Again, it is caused by fruit wounds, and it is considered only to really be a problem in long-term lemon storage.

Packing house practices and treatments to reduce decay. The first thing is we try to destroy any inoculum on the fruit surface. We want to inhibit the development of laten infections by our management strategies as to how we handle the fruit. We do everythin possible that we can do to prevent infection by wound-invading pathogens by using good sanitation. We protect the fruit's surface from subsequent infection through wounding, much as possible, and then we try to use materials that will inhibit sporulation and t spread of the disease to healthy fruit.

So reduced decay, then, is achieved by, then, good sanitation practices in the field and packing house, including chlorination of all wash waters. All water except in one instance which I will talk about in a few minutes are chlorinated in California packin houses at a concentration of 100 to 200 parts per million. We have routine washing of packing line floors in cold-storage facilities and de-greening rooms, and we monitor f plant pathogen resistance to fungicides.

Gloves are used in all handling situations. We use sanitizing agents in the packing house. We use fungicides, and we try to minimize the time between harvest and packing

us in 24 hours, and then also minimize the time the fruit is processed in the packing house to a consumer.

Control of post-harvest citrus diseases in California are achieved by primarily the us of Imazalil and Phyobendasol, or TBZ for the blue-green mold complex. We use sodium otherphenilphynato, SOPP, for control of sour rot. We use an application of 2,4-D as t primary mechanism to control alternary stem-end rot, and then broad spectrum materials that are used in the packing houses would include soda ash or sodium carbonate, sodium bicarbonate, borax, boric acid, lime sulfur that was registered in 1998, and then the of chlorine.

We also have two biological control agents that can be used to control blue-green mold but these have very limited use currently in California.

An example of grade defects. I went to a packing house just this last Wednesday, and they provided me fruit from the floor. This would be the first grade fruit, choice gra and then this is a fruit destined for a processed products.

The choice grade fruit, this is where the fruit going to fresh juice processing would come from is out of this grade. Our grading is done primarily for cosmetic blemishes, again, I will show you some more slides.

Grading, then, is mainly based on cosmetic appearance, including the absence of scarring, pests, and diseases. Fruit with cracks such as a split navel, punctures are excluded, and they go to the cull bin. Peel texture and thickness are also considered the grading of fruit.

This is an example of puff and crease, which can be a problem on both navel and Valencias. This fruit would go to processed products. This is some examples of fruit t sunburned, a split navel that is not too bad, uneven coloring, and different types of surface abrasions. This fruit would be sent to processed products.

This is scarring due to insects, wind, and limb rub, and these are defects due to frui shape. Again, these are the types of fruit that would be sent to processed products.

We do occasionally, unfortunately, have freezes in California. A freeze can cause ice-marking on the fruit here. This fruit, again, would be diverted to processed produ and last year, when we had the freeze, we had quite a bit of internal damage to the fr Depending on the grade standard of the fruit, the amount of damage, most of that fruit would either be dropped on the ground when damage is very severe or sent to processed products.

These are examples of fruit that would be sent to the cull bin, which would be diverte then to either feed or landfill. These would be the split navels, which could harbor alternaria, or fruit with puncture wounds due to long stems or the fruit being punctur by thorns on the tree.

So now I would like to cover post-harvest handling practices. First, we assess minimum maturity in oranges in California. We have a minimum maturity based on an 8-to-1 sugar/acid ratio, and most of the time, this is a portable Boswell press and titration unit so that this can be assessed in the field.

Orange harvesting. We picked the fruit into 40- to 60-pound picking bags. Gloves are used. Here is a guy wearing gloves. The fruit in California are all clipped. This is a picture of the clipper.

The fruit are then dumped into approximately 1,000-pound bins. We do not allow fruit t be picked up from the ground, and many growers actually skirt-prune and lift up the fr from the ground so that no fruit are touching the ground.

Sanitary facilities are provided in the fields for the field workers, and the fruit ar

transported to the packing house on the day of harvest.

Care is taken in the field during harvest to minimize damage because of the potential

for fruit decay, and the consequences of mechanical damage then are increased decay, enhanced water loss, and subsequently, if we are not very good at handling the fruit, can end up with fruit coming out of storage with pitting and rind breakdown here at th stem end due to incorrect clipping and handling of the fruit.

Some of our fruit are early-season navels, and late-season Valencias can be de-greened or treated with ethylene, and the ethylene de-greening process will remove the chlorop from the peel of the fruit so the fruit looks orange. This is an example of a de-green room facility at a current packing house.

After the de-greening or without any de-greening, the fruit then are dumped onto a packing line. In this packing facility, they have an exhaust fan. The exhaust fan woul take off. If there was any decayed fruit in the bin, the exhaust fan in the dumping process would hopefully draw off any spores that would be on the fruit.

Right here, we have a chlorine wash. So the fruit are dumped, go onto a chlorine wash, and we have a trash eliminator here. Here is a picture of the chlorine wash, and, agai 100 to 200 parts per million chlorine are used with oranges.

After the dumping, then the fruit will go through a pre-grade process, and here, then, this middle line would be fruit that would be going to processed products. These white pipes here, then, are fruit that would be either decayed or split or for other reasons that I showed you, and these would be dropped into a flume system that would take the fruit out to culls.

So the fruit that go to juice are conveyed on a conveyor belt away from the remainder of the packing house into a large accumulation bin, and then this fruit is picked up i bulk trailers and transported to the processed products plant.

The fruit that are culled because of decay or other major defects, then, are dropped into a flume system and are carried underground--in this packing house, anyway, carrie underground to an area isolated downwind from the packing house where they are put int these types of containers and transported away either for landfill or for feed.

After this pre-grade period, the fruit go through a pony-sizer, and then in the case o this packing house, the fruit are dumped into a tank treatment. I will talk about this

The tank treatment is optional. Not all packing houses have tank treatments. The type of solution that is included in the tank varies from packing house to packing house. S tanks are equipped so that you can actually heat the solution, but the bottom line is this case the fruit are submersed in the tank for a period of 2 to 3 minutes, maximum.

Tank treatments. Options for the tank mixture varies, about a 50/50 split between sodium carbonate at a 3-percent concentration. In sodium carbonate, the water will be heated to 105 degrees, and the Ph is maintained at about 10.5.

The other major one is sodium bicarbonate, again, at 3-percent concentration. In this case, the sodium bicarbonate is usually chlorinated at a concentration of 200 parts pe million, and the temperature of the tank is usually run between 68 and 80 degrees Fahrenheit.

We also have a few houses that will use borax/boric acid at a total concentration of 6 percent. These tanks are heated to 105, and the Ph is maintained between 10 and 11.

We have lime sulfur which was registered in 1998. Currently, no houses are using lime sulfur.

The average duration for a tank treatment is 1.5 to 2 minutes, 3 minutes maximum. Tank are generally heated overnight when the packing house is not operating to about 140 degrees, and usually, these tank mixtures are changed about every 2 weeks.

Tanks are used in about 30 percent of the orange houses approximately and less than 20 percent of the grapefruit houses.

If the fruit are not treated in the tank, then often the fruit will go over a series o brush beds, and OPP will be applied with just another sanitizing agent.

After either the tank treatment or the OPP wash, the fruit then are passed through a high-pressure washer. This was shown to you by Mr. Martinelli, but this is a Californi high-pressure washer. I just wanted to talk a little bit about the high-pressure washe because this is a very nice innovation and introduction into handling of citrus that h occurred in the United States in the last 5 years.

High-pressure washer technology was developed in South Africa and Israel about 15 to 2 years ago because they had developed resistance to pesticides for scale control.

It was introduced commercially into California within the last 5 years. Most houses now, and I have been told close to 100 percent of all orange houses in California, hav high-pressure washer unit.

Houses without the high-pressure unit will use OPP over the first few brushes or detergent with neutral cleaner to clean the fruit, but, again, this is the minority.

The primary purpose of the development of it was for removal of California red scale, which is controlled in the field by biological and chemical means. This high-pressure washer does a very good job in removing the scale from the surface of the fruit.

We have done extensive tests in California to comie up with recommendations to the industry on what pressures to use to avoid damage to the fruit. So we use 80 to 300 ps The water is chlorinated. We have some packing houses starting to add sodium bicarbona into this wash water. It is a recirculating water system. The water is filtered to rem particulate matter, and the water is replenished on a regular basis.

After the high-pressure washer, then we have another pre-gray area. Again, as Mr. Martinelli indicated, after that fruit goes through the high-pressure washer, if there any rots, that rot is blasted out of the fruit and is very easy to see any decayed fru So that fruit can be culled out. Also, you can see defects better. In this case, they grading under black light so that the decayed spots will show up more readily.

After that, the fruit go through electronic sorting. About 25 percent of our houses no have some sort of electronic grading, and this is great and the trend is increasing.

Then we can divert fruit, then, that are graded as too green or ready to go to processed products that can be diverted to bins from the electronic grader.

Following the electronic grader, the fruit are waxed, and there is a lot of reasons wh we wax fruit. Wax typically have a Ph of 8 to 9, and we have different combinations of that we use.

Following waxing, the fruit will go through a dryer of 3 to 5 minutes, and the dryers are normally run from 90 to 140 degrees Fahrenheit.

Following waxing, the fruit have their final grading into first choice processed products in culls, and following this grading, again, you can see these are the fruit would go down into the flume system out for culls.

The fruit then are electronically sized and stickered and are passed by machine into accumulation bins. We pack our fruit in California either by pattern packing, which is

automated, or there are houses that will also pack by hand.

Once the fruit are packed, they will go through a box sealer. They are palletized and go into short-term storage. Typical turnaround time after packing is 24 to 48 hours an the fruit is out of the packing house.

Alternatives to packaging would be choice fruit going into these tri-wall bulk bins or into either poly or net bags, and, again, then packed into large cartons. A lot of thi fruit now is going to places like Costco and Super K-Mart, et cetera.

Other considerations, then, that I would like to do in summary, packing house sanitation is a guiding principle to everything we do. We use quaternary ammonia or isopropyl alcohol to sanitize the packing house and the packing line. We use high-pres washing of the bins to clean the bins. We monitor for plant pathogen levels on a regul basis for fungicide resistance.

The brush beds are often cleaned during breaks and at the end of the day with quats or isopropyl alcohol. The pack line is typically cleaned at the end of the day. Cull drum are cleaned routinely. It varies from house to house.

The harvest bins, again, it varies how often they are cleaned, and the main key, though, is that in a citrus packing house, we try to isolate the different tasks. Frui that could potentially be contaminated or rotted or have splits or things like that, a that grading is usually done in an area isolated away from the fruit that is ultimatel going to go to the consumer.

Rodent control is actively practiced in our packing houses. Facilities are provided fo our workers for separate areas for lunch and sanitary purposes, and in California, we have an active safety training for all our workers on hygienic behavior and etiquette.

So I have finished in 30 minutes.

MS. OLIVER: Right at 30 minutes. Thank you very much.

Once again, I will ask the committee if they have any questions for clarification.

MS. DONNELLY: I am Cathy Donnelly from the University of Vermont.

I really enjoyed your presentation, and particularly the fruit grading. I think it is very helpful to our discussions.

Could you clarify of the three grades, choice, first, and processed products, is there a distinction made between fruit intended for process that might involve pasteurizatio versus fresh juice without the benefit of pasteurization?

DR. ARPAIA: Preparing to come here was a very interesting experience for me because I never think of fresh juice. My fresh juice is what I squeeze at home.

So I had to start asking questions. The processed products fruit goes to processed products, to like the major juice plants where they do whatever they do. I am not a specialist in that. So I cannot address that.

In asking these questions to a variety of people in the California citrus industry, I was told that the fruit that is sold for "fresh juice," that would go to the juice bars or whatever, that is coming out of the choice grade, and that accounts for of those bulk packs.

MS. DONNELLY: With those grades, are you aware of any microbiological data that breaks down standards based on human pathogens in each of those grades?

DR. ARPAIA: No. I'm sorry. I am not.

MS. OLIVER: Mike?

MR. JAHNCKE: Mike Jahncke, Virginia Tech.

I have a question. On one of your slides, you showed in the packing house, there is some submersion for the cooling, I believe, of the fruits.

Is that used for fresh? Some of those that submerge, does that go into the fresh market, or is that all pasteurized?

DR. ARPAIA: Let me clarify the submersion. The submersion only occurs in those tank treatments. About 30 percent of our houses have tank treatments. The tank treatments, water either contains typically soda ash or soda carbonate os sodium bicarbonate.

In the case of the use of soda ash, the tank is heated to 105 degrees Fahrenheit. So the water is heated. That is to help the efficacy of the soda ash. The soda ash basically--I would not say it sterilizes any fruit wounds on it, but it basically help protect the fruit against subsequent decay by blue and green mold.

When the sodium bicarbonate is used, the sodium bicarbonate is not heated. The tank is usually between 68 and 80 degrees Fahrenheit, the water temperature. That water also h 200 parts per million chlorine added to the water.

Hopefully, the bulk of that fruit will end up in the fresh market.

MR. JAHNCKE: Just another follow-up question. You had slides where you showed the brus with high-pressure wash and things. Do you have any data to show the effect perhaps of high pressure, if there are pathogens on the outside of that?

DR. ARPAIA: Human pathogens?

MR. JAHNCKE: Human pathogens. Is that sufficiently high pressure enough, perhaps, to have that internalized inside the fruit? Are you aware of any data?

DR. ARPAIA: I do not have any data on human pathogens, but when we were developing thi technology for California, I worked with the entomologists who were interested in scal removal aspects with looking at fruit quality. Typically, you can get in excess of 95 percent of the scale removed, both live and dead scale removed, at pressures at around psi.

In the 3 years that we conducted work with navel oranges, which is much more susceptible to damage than Valencia oranges, we did not see severe damage to the peal the fruit at that type of pressure.

The type of damage that you would see, you could get pitting of the peal. The pits typically were not very deep. We know that when you put the fruit through the high-pressure washer, you remove about 80 to 90 percent of the natural wax of the frui So you basically are removing the surface, the very surface of the fruit.

Typically, at least visually, at the pressures we are using, you are not going to see visual damage.

MR. JAHNCKE: Thank you.

MS. OLIVER: Alison?

MS. O'BRIEN: Alison O'Brien, Uniformed Services University.

I would like to just follow up on Michael's question about submersion in 30 percent of the plants that do use the submersion technique. You just said that the majority of th

would go to, if I understood you, fresh-squeezed kind of products?

DR. ARPAIA: Well, no. They are graded as for fresh.

MS. O'BRIEN: Okay, so first, choice.

DR. ARPAIA: So it would be either choice or first grade.

MS. O'BRIEN: But some would go to the fresh-squeezed juice?

DR. ARPAIA: Yes.

MS. O'BRIEN: So, in California, at least there is some submersion of citrus that would go into fresh squeezed, if I understand that.

DR. ARPAIA: I want to make it very clear that the submersion environment in which we are submersing fruit is very, very different than the submersion of those dye uptake t because we are not putting cold fruit into warm solution. The fruit are typically--whe run through the line, the minimum temperature you want the fruit to be is 50 degrees, maximum about 80 degrees. The reason for that is that if you are below 50 degree Fahrenheit fruit temperature, you do not get a good wax application.

MS. O'BRIEN: Okay. Thank you very much.

DR. ARPAIA: So we never put cold fruit, and we never use cold water.

MS. OLIVER: Bob?

MR. BUCHANAN: Thank you.

I have a couple of questions to get some additional information about--

MS. OLIVER: Bob, can you say who you are?

MR. BUCHANAN: Okay. Bob Buchanan, FDA.

Two general questions that I have for further clarification. Do you have an estimate o what percentage of fruit coming from the packing house will wind up in juice productio

DR. ARPAIA: You mean fresh juice?

MR. BUCHANAN: Fresh juice particularly.

Let me give you all the questions. Two, how long is this fruit likely to remain in storage before it would wind up at a juice plant?

Number three, you mentioned several vectors for the transmission of disease in the field while the fruit is still in the tree. Could you give us a little bit more exhaus list of how contamination is likely to get onto the fruit in terms of these plant pathogens?

So it is percentage of fruit going to juice out of a packing house, what are the storage conditions and how long is that fruit likely to be stored prior to production juice, and then, finally, what are the vectors and modes of transmission for plant pathogens in the field.

DR. ARPAIA: Oh, vectors of plant pathogens?

MR. BUCHANAN: Right.

DR. ARPAIA: When we look at the statistics for the California citrus industry, about 8

percent of the fruit are marketed as "fresh fruit." Twenty percent, approximately, goes to processed products. So the processed products I'm talking about the standard juice plant that has to pasteurize juice and everything else that goes wi that. So then we are dealing with that 80 percent.

That 80 percent can be either graded as choice or first grade. The fruit that would go to a fresh juice operation would comie out of predominantly the choice grade. When I h asked the representatives from Sunkist and other independent marketers of citrus in California, they say that many times when they put that fruit into the bulk bin and th sell it, they do not know if it is going to end up repackaged at Costco or K-Mart or something or on the street in Los Angeles or whether it will go to a "fresh juice" operation. So those numbers are very hard to get at within how we handle our fruit because we do not have a grade of fruit that goes to fresh juice because that is siphoned off the choice grade.

Storage conditions. Typically, what we like to have is the fruit picked on day one, potentially held overnight under shade or in a heated condition, again, because we wan run the fruit in that range of temperatures between 50 and 80 degrees approximately, a then the fruit are run over the packing line even in that large operation that I showe pictures from. That fruit typically is on the line probably 15, 20 minutes, and the accumulation bin may be an hour at the most. Those accumulation bins at the packing operation are constantly being filled and emptied.

Then the fruit goes into short-term storage. They like to move the fruit in and out of that storage room within 24 to 48 hours. So then it leaves the packing house.

What happens after the packing house, again, is not really under the control of the citrus industry, that person who is receiving the fruit.

Oranges have a fairly good shelf life for a number of weeks. After harvest if you hold them between about 37 and 41 degrees Fahrenheit, you can hold the fruit for 3 to 4 wee with minimal problems.

I don't know. Does that answer your second question? Do you want clarification on my answers?

MR. BUCHANAN: Yes. Let me ask you a little bit further.

Of the oranges coming out of packing houses, you harvest all year long in California based on your slide. Would the oranges that wind up in the fresh juice industry be onl one variety or would they be a mixture of both the navel and the Valencia, and if they restricted primarily to the Valencia, which as I understand is more of a juice orange, do they handle the fact that they have a limited season? Is there any technologies for extended storage of these so that there would be oranges available for fresh juice throughout the year?

DR. ARPAIA: Navels are not the best for juicing, especially early-season navels, but navels do go through juicing to fresh juice.

In the literature, you can find references to controlled atmosphere storage of Valenci oranges, but, to my knowledge, there is no one that is storing oranges for extended periods of time.

You are thinking like weeks and months, right? Like apples? To my knowledge, no one is holding oranges like apples.

MR. BUCHANAN: Then does that imply that we would have to have, for example, fresh juic manufacturers in California would have to be bringing their oranges in from another harvest location, or would they rely on the navels?

DR. ARPAIA: This is not an area I work in. I would imagine you have enough Valencias

scattered throughout the year into the fall that you could get fresh oranges. I would suspect that they bring some oranges in from Florida during the low times of the year. don't know.

The processed products and the juice side of the industry is not an area that I work with intimately.

I will move on to your third question about vectors for plant pathogens. For post-harvest diseases, again, the major problem we have is with the wound pathogens wh is blue and green mold, and any type of wounding to the peel of the fruit can cause bl and green mold. Blue and green mold are present in the field. They have done a lot of isolation of strains of blue and green mold, both from the field and from the packing house.

So the vector would be man, of course. It could be the tree because citrus trees do have thorns, although they are small. Sometimes you have dead wood on the tree which c abrade or wound the fruit. Fruit, of course, can be wounded during harvesting. So thos would be the vectors.

In terms of insect vectors, I cannot think of anything that would be an insect vector, per se. The major insects that attack the citrus are citrus thripps, but they attack t young developing fruit, and they cause scarring or periderm formation on the peel of t fruit. Again, that is when the fruit are very small.

You have the California red scale that will be present on the surface of the fruit. Again, we have katydid damage, but, again, that usually occurs when the fruit are very small and those effective fruit will either drop off the tree, or if the fruit survive you have a large callous-type tissue develop where the fruit was abraded by the insect

MS. OLIVER: Mike Doyle?

MR. DOYLE: Thank you. Mike Doyle, University of Georgia.

Two questions, Mary Lu. From your perspective, what is the likelihood that intact oranges could be internally contaminated by bacterial pathogens?

DR. ARPAIA: I think very low or nil.

MR. DOYLE: Nil, okay.

Secondly, more of a technical question, what is the pH of a solution, the 3-percent sodium bicarbonate?

DR. ARPAIA: We run it at a Ph 10, 10.5.

MR. DOYLE: What is the purpose of adding 200 parts per million chlorine to that?

DR. ARPAIA: The soda ash is run--actually, I will have to defer real quick to Chuck.

For sodium bicarbonate, what would be the Ph?

AUDIENCE PARTICIPANT: It is also close to 10.

DR. ARPAIA: It would be close to 10.

The purpose of adding chlorine is just that we like to chlorinate all of the water we use. The only place where we do not chlorinate the water in the packing house actually when we use soda ash because the two are not compatible.

MR. DOYLE: How effective would 200 parts per million chlorine be a Ph 10 in terms of killing packages?

DR. ARPAIA: I am not a microbiologist. So I cannot answer that question.

MR. DOYLE: I do not know that it would be very effective. So you may want to look at that a little more closely.

Thank you.

MS. OLIVER: Larry?

DR. BEUCHAT: Larry Beuchat, University of Georgia.

Preceding visual evidence of the growth of plant pathogens, the molds, either in the field or post-harvest, do you have any feel for changes in pH of the tissue in which t molds are actually growing?

DR. ARPAIA: There has been quite a bit of work done in Israel on the Ph of the issue i response to plant pathogens. I do not have that information at my fingertips, but Dr. Shimashan Biyoshiwa from the Volcania Institute has done quite a bit of work, and the group there has done that.

In addition, Dr. Eckert from the Department of Plant Pathology at UC-Riverside has posed extensively what makes the fruit susceptible to post-harvest decay. They have lo at those issues, but I do not have that information at my fingertips.

DR. BEUCHAT: Generally, as I understand, it suggests the pH increases upon growth of molds on fruits or vegetables.

DR. ARPAIA: I do not feel comfortable answering that.

DR. BEUCHAT: With regard to the two commercial products that are applied for the purpose of controlling, I think post-harvest plant pathogens--those are yeasts, as I understand. Do you have any feel for the change in pH there? It is a competitive inhibition process.

DR. ARPAIA: First of all, 99.5 percent, probably, of all the fruit handled in California are still treated with either Phyobendozal or Imazalil. There are only two packing houses that I know of that are using biological controls to control blue mold.

In the one house that I am more familiar with, they use sodium bicarbonate and sodium carbonate, also, prior to applying the biological control agent. So they "try to sanitize" the fruit surface, and then they apply the biological control agent, but they have not been successful in the level of control that you get with the biological control agent. It does not even approach at all the efficacy of the fungicides.

DR. BEUCHAT: Thank you.

MS. OLIVER: We have about 5 minutes left for questioning. We have a number of people still who want to ask questions.

Jim Anders?

MR. ANDERS: Jim Anders, North Dakota Health Department.

I just want to quickly run through the process here again because I am getting a littl confused here. You have an original chlorine wash, right?

DR. ARPAIA: Yes.

MR. ANDERS: Then some 30 percent go to tank treatments?

DR. ARPAIA: Yes.

MR. ANDERS: The rest of it gets a high-pressure wash after that, or do they all get a high-pressure wash? My question is going to be on the high-pressure wash.

DR. ARPAIA: Close to 100 percent of the houses now in California have some form of high-pressure washing.

MR. ANDERS: Then my question on the high-pressure wash is the type of water that is used there and is that water treated.

DR. ARPAIA: The water is chlorinated, and there is an increasing trend to also add sodium bicarbonate to that wash water.

MR. ANDERS: Which means, again, the pH of the chlorine is going to be at around 10.

DR. ARPAIA: Yes.

MR. ANDERS: I agree with the comment. I do not think at 10, chlorine is going to do much.

MS. OLIVER: Dan Engeljohn?

MR. ENGELJOHN: Dan Engeljohn with USDA.

Of the various recycled solutions that are used in the tanks, which you said are filtered before they are dumped at the end of the week, I believe, are any of them analyzed for microbial contaminates or fecal coliforms? Is the starting water potable, is there a standard for that water? Does it meet the U.S. drinking water standard?

DR. ARPAIA: First of all, let me clarify the disposal issues of the water. In the houses that have tank treatments, those tank solutions are typically changed very week every 2 weeks, maximum.

In the high-pressure washer system, that is a continuous recycling system, but because there is a lot of water lost, you are continually adding water to the system. At the e of the day, the water is completely replaced in the high-pressure washer system.

The source of water would be city water. So it is going to meet those standards, and i terms of sampling, to my knowledge, no one is sampling, but maybe someone is. I don't know.

MR. ROBACH: Mike Robach, Continental Group Companies.

I want to ask another question because I am still a little confused on the grade issue and where these fruits end up.

You said 80 percent of the citrus are graded out as whole fruit grade, either choice grade or first grade, and 20 percent are designated as processed product of grade.

DR. ARPAIA: Approximately, yes.

MR. ROBACH: Approximately, yes.

What is the differentiation between the whole fruit grades, the choice and the first grade, and the processed product grade? What is the criteria that is used?

DR. ARPAIA: It is mainly what I showed you. If a fruit has a high level of thripp scarring or it goes through the high-pressure washer and it does not do a good job on scale removal, if there is limb rubs, shape defects with the fruits misformed, then th fruit is going to go to processed products because, in California, we are trying to pa

cosmetically appealing product

MR. ROBACH: What about rind cuts or surface cuts?

DR. ARPAIA: Those would be graded out, and hopefully, it would all go to the culls.

MR. ROBACH: But not necessarily.

Is this a standard grade that all packers abide to, or is it something that each packe determines themselves?

DR. ARPAIA: We have USDA grade standards that you have to meet for certain limits of how much defects can go into what grade.

MR. ROBACH: For those three grades?

DR. ARPAIA: Yes, but we have a lot of different packing houses, and it also shifts wit the market. Typically, you want a completely blemish-free fruit going in the first gra The choice will have some blemish on it, and then the juice stuff would be stuff that a sense of scarring or limb rub or something on it.

MR. ROBACH: My follow-up question, is there anything that prevents a juice processor who may be processing some pasteurized and some unpasteurized juices from purchasing t processed grade product?

If I am producing unpasteurized juice, can I buy processed-grade fruit and use that in my unpasteurized process?

DR. ARPAIA: I am not qualified to answer that question because that is not an area of packing house procedures that I normally deal with. I don't know.

The Sunkist houses, the processed products go to the Sunkist juice plant. Sunkist handles a little bit over half of all the oranges grown in California. The other major packer independent is Sun World, and I believe that they have also their own products plant or a group of people they send products to.

MR. ROBACH: But if I am packing fruit and I have processed-garde product, I can sell i to whoever I want to sell it to?

DR. ARPAIA: I believe so, but I do not know for sure.

MR. ROBACH: Okay, thank you.

MS. OLIVER: We have time for one more question.

Bruce?

DR. TOMPKIN: Bruce Tompkin from ConAgra.

I have actually two simple questions. What do you think the likelihood of fruit going through your system having some hole in it, for example?

DR. ARPAIA: You mean a large hole?

DR. TOMPKIN: A hole.

DR. ARPAIA: A hole. Well, it depends on what you define as a hole.

A visual hole?

DR. TOMPKIN: Yes. Let's go there.

DR. ARPAIA: Low probability, very low probability.

DR. TOMPKIN: Second to that, is there any evidence on the basis of spoilage that occu later on during storage or beyond that would be related to such defects, a hole or whatever?

DR. ARPAIA: I think I see the direction of your question.

We do. The major decay organism we have post-harvest is green mold, and that is a woun pathogen. So, obviously, in the grading process, even with electronic graders, we are catching holes or wounds that are visual to the eye because, if we did, then we would never have a problem with green mold. However, those problems are very well controlled with how we handle the fruit typically.

DR. TOMPKIN: Would those wounds be through to the internal portion of the fruit, to th juice area?

DR. ARPAIA: No.

DR. TOMPKIN: Surface?

DR. ARPAIA: Any wound that would go past the colored portion of the peel or the flabid in my mind would be detected in the grading process in the house.

The wounds that would be just small, microscopic, next to the surface of the fruit, those are the wounds that would get by because you can't see them, but anything that w go to the internal portion of the fruit or through the albedo tissue, I would say woul a very low probability of that getting through to the system.

MS. OLIVER: Thank you very much, Dr. Arpaia.

Our next group of presenters will discuss research results, and following all of the discussion on research results, all the presentations on research results, we will the have questions of clarification at that time.

Once again, I know that some people on the committee still had additional questions, and if there are, Dr. Arpaia will also be here tomorrow morning and will be able to answer.

The first presenters will be Dr. Mohamed Ismail, Dr. Steven Pao of Florida Department of Citrus, and Dr. Mickey Parish from the University of Florida. I remind all three of them that your time is 30 minutes for presentation, and we are keeping everybody to th time in the interest of getting through all of today's presentations.

Thank you.

DR. ISMAIL: Thank you.

Chairman, distinguished members of the committee, I was just going to ask Dr. Arpaia a question about any differences between Florida oranges and California oranges. I am particularly interested, and maybe she can answer that tomorrow, in any anatomical, morphological, or appearance, also any response to storage temperature.

We are definitely pleased to be here because we believe in cooperation, collaboration, and in dialogue. We also believe and appreciate being part of the regulatory process. share this committee's concern for public health. We clearly understand Food and Drug Administration's mandate to protect consumers against foodborne illnesses, and we have been working with the Food and Drug Administration on fresh juice regulation for sever years. We hope that this cooperation will foster an atmosphere with science and commo sense. Science and common sense can go hand in hand guiding our actions, your actions,

FDA's actions, and our response to these actions.

From what I have seen so far, you have been given an agenda that appears to be biased. You will ask some questions. The answers to all of them can be yes, yes, yes. We ask y to be objective and do not let scientific integrity be compromised.

I wish to preface my presentation by stating that based on our review of the literature, there has never been a documented case of foodborne illness attributed to fresh citrus fruit. There has never been any case of foodborne illness attributed to citrus fruit. In fact, I am willing to go on record stating that none of the documente foodborne illness attributed to fresh, non-pasteurized juice--and in that case, I woul say citrus juice--has been traced to fruit. It has always been lack of or breakdown of good manufacturing practices, and the absence of standard sanitary operating procedure that led to the recent and not so recent incidence of orange juice-related foodborne illness.

According to a survey of the literature, six incidents of orange juice-related foodborne illness have been reported since 1944, 55 years. None of these cases have conclusively implicated fresh citrus fruit as the causal agent.

I would like to show you a table to show you these cases, and I do not see my slides o the screen. So I have prepared a transparency which I can put on an overhead, if you c get me one, please.

I think you can see here the title of my presentation, which is Infiltration of Human Pathogens in Oranges, Fact or Fiction. My name is there, and I am the director of Scientific Research for Fresh Fruit for the Florida Department of Citrus.

As I mentioned, no documented case of foodborne illness caused by citrus fruit. It has always been lack of good manufacturing practices and standards, sanitary operating procedures. I think we have one more "p" here than we should, and it is usually the culprit. In 55 years, 60 cases of--if you cannot see that, I am going to guide you through it.

In 1944, in Cleveland boarding house, a case of typhoid fever, salmonella typhi, 18 cases, 1 death, caused by asymptomatic food handler.

In 1992, in India, a gastroenteritis, E. coli was involved, 6 hospitalized, no death. Probable cause was poor sanitation, lack of GMPs, open-air roadside stand on dirt road within a few years of a town dump.

In 1995, Florida, the salmonella in the Winterhaven area, the so-called Disney case, 6 cases, 7 hospitalized, no death. Probable cause, inappropriate sanitation, breakdown i GMPs, and close proximity of salmonella vectors.

In 1999, we had three cases, one in Australia and two in the United States, and the tw in the United States were caused by one company, and it was related to imported juice tankers.

The one in Australia was not determined exactly what the cause, and it happened in 1999, 488 cases and 8 hospitalized.

So, again, there has not been any confirmed cases of foodborne illness caused by citru fruit, by the fresh fruit.

The overwhelming safety record of citrus fruit is generally attributed to the following. Number one is that citrus fruit has a protective rind that insulates the interior against contamination by human pathogens. The rind can be effectively scrubbe sanitized, and even heat-treated without impacting the internal quality of the fruit.

Citrus fruit has low pH, and the question was raised how low is low. I think grapefrui

can be 3.5. Oranges can be 3.8 to 4.0. It does provide a less hospitable environment t the development of disease-causing microorganisms.

Citrus fruit is subjected to packing house treatment that ensure effective removal of surface microflora. No E. coli or salmonella was found in packed citrus fruit, on pack citrus fruit, and we did a survey. We looked at eight packing houses. We did not detec any salmonella or E. coli.

This morning, Madam Chairman, we plan to provide your committee with information on th Florida citrus fruit and fresh citrus juice industries and address the controversial i of infiltration.

Our presentation will cover three general areas, an overview of the fresh citrus juice regulation, and an evaluation of the Food and Drug Administration's preliminary study the potential of infiltration, growth, and survival of human pathogens within oranges, this will be presented by Dr. Mickey Parish, professor of Microbiology, University of Florida, and finally a presentation by Dr. Steven Pao of the Florida Department of Cit that will present both Florida Department of Citrus and University of Florida studies the infiltration, survival of salmonella species in Hamlin oranges. That, as I said, w be presented by Dr. Steven Pao.

At this point, I would like to call on Dr. Mickey Parish to give us an evaluation of the study that was done by the Food and Drug Administration.

DR. PARISH: Thank you, Dr. Ismail.

This is something that is extremely important. I am going to be going rather quickly, and I apologize for that.

I hope that you will be able to stay with me. I am a test case this morning. I walked over to Starbucks and I consumed a pint of fresh-squeezed Orchid Island orange juice. will be here on Friday. You can check back with me to see if I am ill.

First of all, let me just say that I have never received any funding from the fresh juice industry. My travel expenses are paid by the university. I have no ax to grind w anybody except for the fact that we need to use science, and not emotion, to cover thi issue. This is a highly complex issue, and I want to discuss a few things related to F studies.

FDA has an obligation. They are understaffed, underfunded, and under the gun all the time. These folks honestly are asked to do yeoman's work in all cases, and it is very difficult for them to do that.

I must say that I have grave concerns about publication on the web of information that has not been adequately peer-reviewed, and I do not believe the studies published were adequately peer-reviewed.

Let me just discuss briefly the Hill and Wenzel paper that has referred to FDA. It states that they use frost-damaged oranges. They, indeed, did not. They used oranges t had been frozen. So that, ice crystals were formed in the peel. There would be a probl with the peel and the micro holes that FDA is concerned about would certainly have bee seen in frozen oranges.

Secondly, in that same paper, they state that half the fruit having micro holes were contaminated with microbes attributing back to Hill and Wenzel. Actually, Hill and Wen said half of the fruit having microbes also had micro holes. This is a distinction tha indicates to me this is put together very rapidly and was not adequately peer-reviewed

In all actuality, only 20 percent of the fruit having micro holes were contaminated with microbes in the Hill and Wenzel study.

In the fruit infiltration studies, FDA applies the inoculum 10 million cells after removal of the residual stem material. My concern is the process of removing that stem material, which would not be done in the industry in Florida. It may have caused fissu to develop in the peel.

Again, the fruit infiltration studies, 80 degrees C. water bath for 1 minute was used to sanitize contaminated surfaces based on Dr. Pao's work. Unfortunately, Pao's resear indicated that ADC for 1 minute when the inoculum is applied on the stem scar will onl produce a 4-log reduction. That means that there would have been thousands of cells remaining on the fruit surface. So the handling of the fruit after that point could possibly lead to cross-contamination.

This calls into question to me whether the cells in the resulting juice came from the internal or external portions of the fruit.

The FDA study says that the fruit was cleaned and rinsed. Were they clean? I hope they were. If not, then I think that that's a real issue that needs to be addressed. Also, juicing operation itself is not typical of what's used in the fresh squeezed industry Florida.

When we look at the survival of pathogens, FDA diluted their pathogen cultures directly, direct cultures in nutrient broth, in 10 percent peptone. Peptone is a nutri It will promote the growth of organisms, and it does have buffering capacity such that pH could be altered. Again, also, were the cells growth phase or stationary phase? An overnight culture? I don't know.

When they discuss waterborne contamination, they talk about this high-pressure washing system, and I must state that the implication that I understand is that spray washing could compromise the peel integrity. They refer to the study by Petracek. The Petracek study actually investigated a specially designed high-pressure water system that, unti few minutes ago, I thought was not used in the Florida citrus industry at all. There i evidence that standard spray washing compromises peel integrity.

Waterborne contamination, this is very interesting. Potential internalization from hydrocoolers' dump tanks and rain, the Florida citrus industry does not use hydrocoole dump tanks or flume systems of any kind. Oranges are not immersed, period.

The rain issue is highly speculative. Basically, FDA's studies that were conducted use a temperature differential of roughly 33 Celsius degrees to force pathogens down below surface of the fruit. You would not see a temperature differential of 33 Celsius degre due to a rainstorm in Florida. Additionally, most of the fruit is harvested prior to t rainy season, the summer rainy season in Florida.

FDA states that Pao and Davis found that immersing inoculated oranges in hot water or various chemicals produced a certain log cycle reduction. Actually, that reduction was reported only for the chemical solutions. The hot water treatment actually reduced it greater than 5-log cycles.

We hear a lot about alternative processing techniques. Let me just briefly state the Tribunal I follow this quite closely. At the present time pulsed electric field and UV light are not applicable to orange juice. Minimal thermal processing is, high-pressure processing is; however, this equipment is enormously expensive. Additionally, for oran juice, the company that makes this equipment is tied into an exclusive agreement with Minute Maid Company; therefore, it's not available.

In a recent review of these technologies, my good friend Chuck Sizer says that most of the fruit juices such as orange are sufficiently robust to tolerate thermal processes the range of 90 to 100 C. This is not correct. Fresh squeezed juice has very delicate flavors that are affected by thermal processing, and the only viable alternative for t at this time is pasteurization.

A need exists for data to address risk assessments. What's the probability that pathogens will get into the fruit on tree and that that fruit will somehow get into th juice stream? What's the fate of the pathogens introduced into the fruit? We have not conducted an adequate risk assessment. Executive Order 12-866 requires that when these regulations are going to impact an industry such as this, perhaps put the industry out business, that risk assessments be conducted.

Risk assessments are critical. There's no evidence that the outbreaks from orange juic are due to internalized pathogens. There is plenty of evidence that the outbreaks--and they do occur, and this product can have some minimal risk associated with it. The evidence is that it's a breakdown of sanitation. That's where the emphasis needs to be placed, not on the internalization.

Industry end-product testing has been negative for Salmonella or the pathogenic E. coli. You've been given a list of questions. My take on the questions and the comments I've heard this morning is that: Are we going to regulate based on science or emotion? questions appear to be written in a way to elicit a response and not necessarily to clarify the issue. My question would be: Will FDA choose to regulate a commodity, an industry out of existence based on hypothetical risk or based on actual risk assessmen

Thank you very much.

[Applause.]

DR. PAO: Good morning. It's good to use your own computer. You know how to operate it.

The title of the presentation, "Infiltration and Survival of Pathogens and Its Implication on Fresh Juice Safety." I would like to report to you the preliminary findings on microscopically observed differences between dye and bacterial infiltratio secondly, location of viable bacteria in orange fruit after forced infiltration create a large temperature difference, a method utilized by FDA; thirdly, sanitizing orange f by hot water to achieve a greater than or equal to 5-log reduction in fresh juice.

To determine if dye is a good indicator for bacterial infiltration, Dr. Parish and myself inoculated 10 decalyxed Hamlin oranges with dye solution and Salmonella-express green fluorescent protein. Following FDA's approach, the inoculate fluids were refrigerated at 4 degrees C. for three hours before sectioning and observation. This p of pictures were taken from the central section. The picture on the left-hand side sho dye solution can infiltrate through vascular bundles and spread around. However, the picture on the right-hand side shows bacteria tend to localize at the near-surface are

This pair of images also shows the difference between dye and bacteria. The bacteria o the right-hand side stay on the top. Our results suggest differences between dye solut and bacterial infiltration were observed microscopically. Dye penetrates deeper than bacteria. Dye spreads laterally; bacteria do not. Bacteria were not observed in every vascular bundle that were infiltrated with dye.

To determine the location of viable bacteria after forced infiltration, Dr. Parish inoculated 67 freshly picked Hamlin oranges and inoculated the oranges with Salmonella After a refrigeration process, the fruit were cut into four layers and separately plac in a sterile sampling bag and massaged and squeezed, with or without addition of pepto water to assist the recovery.

On the other hand, my lab has tested eight groups of 10 decalyxed Hamlin oranges, so the cap, the green cap removed so to create a fresh scar. And similarly inoculated fru was placed in refrigeration condition and was first cut into four pieces, but only the three layers were tested. And the refrigeration time was either three hours or two day And the sample was smashed--a composite ten pieces of fruit sample were smashed in jui blender.

The result shows from Dr. Parish's data, 67 fruit--tests on 67 inoculated fruit had

positive result, and that's because that's the top layer right on the surface. On laye only 1 out of 67 fruit were found positive. There is no deep penetration indicated by layer 3 and layer 4.

On the Pao three-hour study, the three hours of refrigeration time, five group out of five group had positive on top layer, and four out of five had second layer, and no de penetration on layer 3. However, after we refrigerate the same inoculated group for tw days, I was not able to recover bacteria on layer 2. The ratio of positive contaminati on the layer 2 from my data is because the fruit I tested was freshly decalyxed.

The last part of my report, I would like to show you our evaluation on the sanitizing effect of hot water treatment. In this study, Hamlin oranges were immersed in E. coli culture for 15 minutes at 25 Celsius and inoculated fruit were air-dried for two hours 25 Celsius, and fruit were either extracted by a commercial juice extractor or immerse hot water at 80 degrees Celsius for one or two minutes. At the same time, fruit were taken--air-dried fruit were taken, placed in sampling bag, and shaked with peptone wat with shaker for surface count. At the same time, fruit were also taken, placed in juic blender to determine the macerated juice count.

This figure shows--note the data represent the means of three replications, and the inoculated fruit surface had 5.4 log CFU/cm^2, and no significant difference was observed between surface count and the macerated juice count, except the first one was expressed by centimeter squared and the other one is by volume.

Therefore, the first bar on the figure indicates our inoculation level, and after juic extraction of the inoculated fruit, we can see on the B bar the counts reduce near 2 l and the reduction was contributed by commercial juice extraction.

For the C and D treatment, fruit were inoculated with--were treated with hot water treatment. This is an immersion process. It's not a common industry process, but it's designed to show one way to achieve 5-log reduction. It's for research purpose at this time.

The fruit were soaked in hot water for one to two minutes before extraction. The E. coli counts were less than one per ml; therefore, this study demonstrated a 5-log reduction from juice to juice.

Our preliminary conclusion indicates dye solution is not a reliable indicator for bacterial infiltration study. Bacteria localized at surface and near-surface areas aft forced infiltration. No recovery beyond near-surface area--no recovery we see in fruit after cold storage for two days. Sanitizing fruit can be a means to achieve 5-log reduction of fresh juice. In our study, we demonstrate a 5-log reduction by surface ho water treatment, and these results confirm our previous report using late-season Valen oranges, which was published in Journal of Food Protection in 1998, Issue 7, I believe However, it was unfortunately cited incorrectly in the paper published by FDA entitled "Potential for Infiltration, Survival, Growth of Human Pathogens with Fruit and Vegetables."

I have prepared 32 copies of my presentation that I will provide to our chairperson after my presentation. Thank you.

MS. OLIVER: Thank you very much.

[Applause.]

DR. ISMAIL: Dr. Oliver, how much time do I have left?

MS. OLIVER: About two minutes.

DR. ISMAIL: Well, I would just like to conclude this presentation by saying that havin demonstrated that the 5-log reduction is achievable, it seems that the Food and Drug

Administration is upping the ante for the industry. Faced by a recent outbreak of illn caused by consumption of fresh juice produced by one company, FDA officials designed b the dye infiltration and the microbial internalization infiltration study in which, as know, 10 million organisms were placed on the button area of the fruit that was kept a degrees Celsius, refrigerated to 4 degree over a period of three hours; the temperatur the fruit dropped from 37 to 11, just creating a condition which the internal atmosphe the intercellular spaces of the fruit have shrunk, creating a vacuum, a sink, forcing microbial-laden solution to penetrate the fruit.

So these are highly exaggerated, highly experimental conditions, and we are not agains that. Anybody can do anything they want to do. But to say can human pathogens theoretically infiltrate citrus fruit, yes, it can. Anything can happen theoretically. think theoretically we can have contamination if you have a load of oranges collide wi load of cow manure, and somebody takes that fruit, puts it in storage, then take it, w it, clean it, and then juice it. You will definitely have a theoretical situation unde which infiltration can take place.

To the Committee, we recognize the challenge that is posed to you--

MS. JACKSON: Dr. Ismail, that was your additional two minutes.

DR. ISMAIL: Was it additional or--

MS. JACKSON: You were given a total of 30 minutes for your three presenters, and your 30 minutes is now up.

DR. ISMAIL: Thank you very much.

MS. OLIVER: Our next presenter is Jur Strobos with Olsson, Frank and Weeda.

DR. STROBOS: Good morning. My name is Jur Strobos. I'm a physician. I'm representing a consortium of four companies. The four companies are the Fresh Juice Company, which is part of Saratoga Beverage; Orchid Island Juice Company; Perricone Juices in California and California Day-Fresh. Two California companies, two Florida companies.

It has occurred to me, as I went through the agenda, that there would be a lot of questions about HACCP and the HACCP programs, and to a certain extent, I think I have experimental data that it does seem to me that we can spend a little bit of time on th HACCP programs.

This particular consortium was formed just three months ago when the issue--which was little bit of a surprise to us--of internalization was raised. We've begun testing. We obviously haven't--as FDA, I think, indicates in its studies, we're talking about preliminary tests, and we're also talking about sort of a history of the safety record

Again, we're here only to talk about citrus juice and the issues with regard to citrus juice. As I think Dr. Parish indicated, taste is a significant issue. People like fres citrus juice, so there is a demand for fresh citrus juice, and I think our goal here t is to try to figure out how to make sure that none of the outbreaks that have taken pl in the past ever occur again.

Part of my goal here is to present some of the actual real-time data. One of the comments in the FDA summary is that there are no real-time data. In fact, there are because these four companies that I will be discussing and some of the data--we have b actually, as part of the HACCP program, collecting real-time data, and I think that th real-time data demonstrates some significant differences between some of the laborator data. I think some of the explanation for those differences is found in some of the discussion that you've heard. But I think it's important that we set the real-time dat the standard, and then I think the laboratory data then has to meet a burden of qualit order to establish that there is some sort of internalization.

Just to give you our position for the HACCP consortium here--and, again, these are fou companies that represent--it's a very small industry, the fresh juice, fresh citrus ju industry, but these four companies represent, we think, probably over 50 percent of th industry. We're not talking here about, you know, fresh fruit that may be delivered to storefront or something like that where it would be squeezed, as was perhaps some of t discussion earlier about California. We're talking about a small group of four compani who basically only produce fresh citrus juice.

We support the mandatory HACCP program that is proposed in the April 24th rule. We support the components. We believe--we're not asking--I mean, I heard Ms. Girand this morning, and we support in large part her advocacy that that rule should be finalized. We're not asking for some sort of experimentation on the public here. What we're askin for this Committee to look at the Florida model, the Florida model which is used by th four companies, and say, Does that model--which we think has provided a 3.5-year recor safety--does that provide an appropriate control?

We don't particularly want to stand here and defend industry practices. There was some discussion of what happened with the Sun Orchard episode. There is a warning letter th FDA had issued on August 20, 1999, which is a public document, which does indicate som the GMP and sanitization deficits with regard to other industry practices, and we're n here to defend those practices. In fact, we're here to support a program in which thos practices would not be permitted.

We think that it's important to look at the outbreaks. All the outbreaks appear to hav been associated with post-extraction contamination, the example given of ice entered i directly into fresh frozen juice, unpotable ice entered into fresh juice as an example think that we've established a record of a cumulative 5-log reduction through the extraction process that is safe.

We are thinking about enhancing this with actually pre-release testing with microbial test results before that. And, of course, I think we all--those people who are into HA believe that GMPs, sanitization, SOPs, and a firm HACCP program with multiple layers o controls is really the goal here.

Under this system, we think fresh citrus juice is proven safe, and we think there's a 3.5-year track record at this point of in vivo microbial data that establishes that internalization does not occur in practice.

Briefly reviewed, the Florida HACCP program began with the Disney episode, otherwise referred to by the CDC as "the theme park episode," in November 1995. The Florida program, which is in Florida regulations, which were provided as part of your package, became effective in February 1996. It is a grove-to-customer control system. is possible to create a system like that, and we are an advocate of that.

The record, again, is that we have tested for pathogens, human pathogens--Salmonella and E. coli--in, between the four companies, nearly 18,000 batches, which includes 2.7 billion citrus, and at this point have not had a positive result for Salmonella or E. coli.

One of the questions you're being asked is whether pathogen internalization into citru is theoretically possible. It's a difficult question to answer because are we talking under laboratory conditions, are we talking under naturally occurring conditions, or a we talking under the mandatory HACCP conditions that have been established and in prac for three and a half years and which are used by these four companies. And I think tha makes it difficult to discuss the theoretical question that you have been assigned to discuss.

There have been a lot of questions here about what goes on in this mandatory HACCP program and where are the safety controls, and I think in order for this Committee to assess the realistic possibility of internalization, we need to discuss specifically w those HACCP controls are, and I think we need to divert some of the discussion to that

There is a fruit selection process. This fruit selection process is not merely a quality issue; it is also a safety issue. There are three different stages. There's a delivery inspection, which looks at whether or not these are the kind of fruit that di come from, you know, grove-picked fruit. There is an initial grading that occurs right after it's unloaded. And then after brush washing--and, as you know, brush washing can induce--if an orange does have some sort of scar in it or has some covering over it, b washing will, you know, reveal some of the defects in the fruit. And so there's a thir grading step or fruit selection process that occurs after the brush washing.

Fruit handling is an issue. I think we've discussed the fact that none of the companie that we're talking about under this Florida HACCP program use fruit immersion techniqu so fruit immersion is sort of not an issue here.

There was another question that came up as to whether or not navel oranges are used. Navel oranges are not used in this process. It's basically either Valencias or Hamlin oranges which do not have the sort of involution at the floral end that could be a sou of contamination during the extraction process.

The fruit all undergoes then a surface sanitization, brush washing, pinpoint extraction. In the records you have before us are documents that we submitted to the F and also discussed at the Florida symposium on 5-log reduction that demonstrates actua reduction of organisms from surface contamination through to the end of sanitization.

These steps are conducted at a single site, as I think you saw from the Orchid Island demonstration. The sanitizers, there are specific Florida requirements with regard to sanitizers. The sanitizers being used in this program are being used at pH's where the effective, not at elevated pH's, under this particular HACCP program.

The brush washing has--there was a question as to whether there has been demonstration whether brush washing reduces pathogens, human pathogens on the surface. Orchid Island demonstrated that, and we've also demonstrated that with surrogate organisms. Again, t 5-log reduction data were submitted.

Rinse water is--you know, potable rinse water is used. Equipment is sanitized. There i microbial testing of basically every batch, and this I think is probably the best data that you're going to see today. We have the four companies here. We've given you an estimate of the amount of citrus that have been processed. These are--you have to give this so I can work it.

These are the actual number of batches for which we have records of testing. At the Fresh Juice Company, we're talking about 7,788 batches in the late three and a half ye At Orchid Island we're talking about close to--a little over 3,000 batches. So we're talking about actual human pathogen test results in nearly 18,000 batches. We haven't a single positive result. That represents 2.7 billion oranges.

I think that, again, these are the data that are important to look at. These are right now, you know, publicly available data. They've been publicly available since we submi them to the docket in November.

We had additionally submitted similar data to this Committee back in 1996. At that point, of course, we didn't have this volume of data, but we think this is a fairly impressive demonstration that at least when you run a HACCP program that Florida sort specifically created to deal with this risk, you do not have a problem with microbial internalization.

In terms of experimental design and theoretical risk, I think it's clear that the citrus peel is not impervious to needles. If you use a hypodermic needle to inject organisms in, if you use a lipophilic dye, as was demonstrated earlier today, or if yo use pressure inoculation of microorganisms, you can probably get organisms through the citrus peel. But we don't believe that these are realistic test conditions that are

consistent with a mandatory HACCP program that's been in force in Florida for three an half years.

We don't think immersion in contaminated water represents a realistic test condition. You know, one question arises is when this hypothetical inoculation in the stem scar occurs. Again, we're talking about fruit that are graded. We're talking about fruit th are not dropped. We're talking about fruit--you know, obviously the stem scar can't be inoculated on the tree. As Dr. Parish was indicating, you know, how that stem scar is removed in the laboratory can have an effect. You know, we don't see any circumstance practice where there's pressure gradient inoculation or these temperature gradient inoculations. We're talking about a 60 degree Fahrenheit temperature gradient that we don't--I mean, I think if there was a rainfall in the Florida harvest season that prod a 60 degree temperature drop, we'd hear about it. It would be a very pleasant experien

Some of the other unrealistic test conditions we're looking at is exposure to 7-log concentrations of pathogens, and Dr. Parish indicated some of this before as to whethe we're talking about growth phase or stationary phase organisms. These are issues that probably not naturally occurring contaminants.

We have competitive organisms out there. I think we had a whole discussion this mornin about a number of plant pathogens that may serve as competitors to human pathogens.

I don't think that these--no one of these issues eliminates risk, and that's why we're in support of a HACCP program. Our concept is that a HACCP program has multiple layers risk and multiple layers of reduction of risk. And when you begin to look at each of t layers of reduction of risk, I think you make the likelihood of juice contamination un a mandatory HACCP program zero.

We are going to hear data later today about how two oranges out of 55 had some internalization. We don't know whether these were oranges that would be acceptable for juicing. We don't know whether these are post-brush-wash oranges that would be accepta after brush washing.

Our biggest concern--and we've begun doing some laboratory data, and our biggest concern is we've discovered a real problem with cross-contamination in the laboratory. Unlike in the industrial setting where we've been able to establish that we can significantly reduce surface contamination using the methodology that we've done and f which we've provided data to the FDA, it's been our experience in the laboratory that type of techniques used in the laboratory to surface clean are not always effective in laboratory setting the same way they are in the industrial setting.

We know that Dr. Pao has a significant amount of experience with this, and my own impression in reading Dr. Pao's work over the last year or the last couple of years is that his experimental techniques have gradually gotten better. It's one thing to read techniques and try and duplicate in the laboratory, and it's another to really underst how these techniques work in trying to avoid cross-contamination.

You know, we have attempted to use this laboratory surface heat treatment in our own studies, and we clearly have a learning curve in terms of using that in a laboratory setting and trying to figure out whether or not we can avoid cross-contamination and whether or not there's residual organisms on the surface of the orange.

We had some discussion of dye earlier today, but I think that the issue of whether the surrogate is an appropriate one is a serious one.

You know, I have talked to a number of chemists. I think Dr. Pao's data make the point that you would expect penetration with the kind of dyes used based on partition coefficients just of the chemical itself. Stem scar inoculation is not possible in the grove. Fruit were not selected properly. A lot of this is duplicative of what I have j gone through before.

But I want to emphasize the fact that there are controls in place with regard to a lot of these issues, and so when you look at laboratory data, I think we need to assess whether those laboratory data are applicable in the field and in natural conditions.

We conducted some recent testing, and I'm going to show two sets of testing. One is some preliminary testing where we got some data and we were concerned about some of th data, and then we went back to the laboratory--again, this is in the three-month time period that we were given here. We went back to the laboratory to identify what some o the issues were in terms of our laboratory testing. We used the same temperature gradi although we don't think that's realistic. We used the same sanitization, although we didn't have any particular personal experience with that sanitization.

We did think it was important because we know that there's a lot of cross-contamination. When you use cone compression in the laboratory, you are going to cross-contamination from the surface into the juice. And so we started off saying, wel how can we establish a decent control for the baseline contamination that's just going occur as a result of cross-contamination from the surface?

So using the FDA data, we said, well, FDA has sort of indicated that without a temperature gradient, there's no internalization, so how about if we use that as a con and then we'll subtract that baseline cross-contamination that occurs with the no-temperature control against the temperature gradient control to try and see if we c separate out what's due to internalization and what's just due to cross-contamination.

In this testing, we basically started off with an inoculant at 25 degrees. We ran 30 oranges in three sets. We did the same steam sterilization. More detail about this stu is provided in the documents we've submitted.

What you will see and what we noticed when we first started doing this is that the amount of organisms we recovered in the juice were highly variable amongst our sets. I mean, we had from 0.85 to 1.15 to 2.52 log CFU/ml, and we began wondering about that.

We looked at the 37 degree oranges, and we had similar variation in terms of using the same technique that FDA was using, but this time using whole oranges rather than half, sliced oranges, and using an FMC extractor rather than using cone compression. And we found less internalization with the temperature gradient. So this struck us as a littl bit odd, and we went back and tried to look at our sanitization technique, and we had an individual who had worked with us in the plant during our 5-log experiments, and we decided to compare using that individual doing our sanitization technique versus anoth individual who was basically just reading the protocols and working in the laboratory.

This is our sort of next set of data. If you use non-inoculated fruit which is sanitized, you get no organisms, as you would expect. If you inoculate the fruit and d sanitize it but use an FMC extractor--and here we're starting again with 10^6 organisms, so we've actually in this little study once again validated, you know, the reduction you get just from the extraction technique alone because we came down from a inoculum of 10^6 to an unsanitized cross-contamination of 3 log.

We did this another time using, you know, the other performer, and we ended up with basically similar results, validating again the log reduction due to the extraction technique. We then basically had the sanitizing done by someone who was reading the protocol carefully--

MS. JACKSON: Dr. Strobos, you have two minutes left.

DR. STROBOS: Okay. And we discovered that with inexperienced sanitization we had the same level of cross-contamination as if we had no sanitization whatsoever. When we use experienced sanitizer, we ended up with no cross-contamination.

So I think there's a significant learning curve involved here in some of these internalization studies. I think Dr. Parish has discussed some of that as well, as wel

Dr. Pao, and I think we need to look at these data as being preliminary data. Cross-contamination is hard to distinguish from internalization. It seems to be random It's experience-related. And we think it's an endemic methodologic laboratory error in most of the studies that have been done in this sort of two- or three-month time frame

There is published information on naturally occurring human pathogens in citrus fruit. We have data on 2.7 billion oranges basically tested in 20,000 batches of fresh citrus juice without any evidence of human pathogen contamination. We don't think the laborat theoretical internalization data duplicate the natural conditions. We think that based the scientific data we're presenting on what actually we've seen in terms of results a these laboratory data that there's a burden to establish support for likely internalization under the HACCP conditions that have been in place for three and a hal years. And, again, we need to go back and look at the fact that the outbreaks appear t implicate post-extraction contamination, and, again, as I said earlier, we think fresh citrus juice is safe under the mandatory HACCP programs, which includes careful fruit selection to ensure against internalization, 5-log surface decontamination and appropr extraction methodology, a system in place that precludes post-extraction contamination and a final layer of security by pathogen testing.

In answer, we believe the answers to the question, therefore, is that theoretical microbial internalization is most likely to occur in unrealistic settings. There's no public health risk related to this putative internalization. And established HACCP pro techniques prevent pathogen transmission, and use of a warning label would be false an misleading as applied to fresh juice that is made under this kind of a HACCP program.

That's all I had to say.

[Applause.]

MS. OLIVER: Thank you very much.

The next research presentation is by Dr. Arthur Miller, a senior scientist with FDA's Center for Food Safety and Applied Nutrition.

DR. MILLER: Well, thank you, LeeAnne, and good morning. Let me just adjust this mike s it doesn't fall on my foot.

It has been brought out that the proposed HACCP rule required a 5-log reduction performance standard in unpasteurized juice based upon this Committee's recommendation and among the assumptions being made was that pathogens are located on the surface, no the interior of citrus. And, therefore, we wanted to evaluate this assumption that pathogens are confined to the surface of fruit. And so this morning I will be presenti the results of published literature and our interpretation of that literature as well number of studies that were conducted in our laboratories that: first, investigated th potential for dye uptake by citrus fruits; secondly, studied the potential for pathoge infiltration into oranges; thirdly, looked at the potential for pathogen survival and growth within oranges; and then, finally, looked at the potential for pathogen growth orange juice.

We've heard quite a bit this morning about potential for environmental contributions a vectors to pathogen infiltration. I'm not going to belabor the point. I do want to, however, make sure that we're parsing out some of these issues that people appear to b going back and forth on. And in our document that's been made available to the Committ as well as publicly on the World Wide Web, we provided a table that really broke down we knew, what we didn't know from the literature, from a number of these sources. Some the literature was on citrus, some on non-citrus, and it's important to bear in mind t many of the issues that we're discussing here today, we really have very little publis literature to serve as guidance.

Much of the literature about environmental sources comes from non-citrus studies. We know about infiltration through anatomic structures such as buds, leaves, through the

stomata, fruit. We've discussed potential for infiltration by surface damage. There's the potential using studies from other commodities, especially tomatoes and apples, wi vectors such as insects, birds, and dust.

Again, not only from citrus data, we know that hail and frost damage can cause damage in some of these commodities.

I did want to mention one aspect, because we've been focusing on high-pressure washing quite a bit, that it is used, as we've been describing, in the industry. However, we a not aware of any data that shows if there is a possibility for microorganisms from the surface to be internalized on sound fruit. We have no information either about whether microholes may be a factor here and whether penetration can occur through this mechani

Dr. Ismail very eloquently, I would say, described how some of these microorganisms ma get inside, through temperature differential and taking up of these pathogens within t fruit by that mechanism. And the real question that we need to be considering here is is the likelihood of that occurring.

Now, if the microorganism can get inside, we do need to know something about the survival and growth characteristics. We have virtually no information on this in citru fruit. We do know that Salmonella can survive and grow in tomatoes and apples. We know that E. coli 0157:H7 can survive and grow in apples. We do know that survival and grow can occur of lactobacillus, leuconostoc, and yeast in orange juice. And a study report Peno Fratamico from USDA ARS has shown that E. coli 0157:H7 can survive in orange juic for 24 days at refrigeration temperatures. And I'll also highlight the fact that this the particular strain that we used in our study.

The literature on the natural occurrence of microorganisms in juices is quite limited as well, and I think we need to, again, parse out the difference between occurrence in oranges versus occurrence in juice. And there is a little bit of information that we k on non-pathogens from one of Mickey Parish's papers. There was also submitted to the F survey that was done by the Florida Department of Citrus indicating that 4 percent of small juice processors had generic E. coli in the product. And, again, I will emphasiz that we are not aware of studies showing pathogens specifically in oranges, separating that from the question of in juice.

So, with that as backdrop, we decided to perform a number of studies, including an initial assessment of the potential for external substances to infiltrate oranges and grapefruits.

In this case, we used sound fruit that was obtained from commercial sources and consisted of fruit from both California and Florida. The fruit was individually inspec for defects, which included breaks in the peel, areas of decay, softness, or any other features considered atypical. We felt that the individual inspection was more rigorous than commercial inspection procedures because we visually inspected each one by hand, spending time on this inspection.

We used Brilliant Blue as the dye at a concentration of 200 mg/L. As you can see from the photo, we completely submerged this, and you can also see from the slide the conditions. We submerged them for 10 minutes at a variety of conditions, including fru at 21 or room temperature, and the dye/water solution at 4 degrees, or refrigerator temperature, room temperature fruit in water, and cold fruit and cold water.

Afterwards, the fruit was rinsed with tap water to remove any excess dye, and then we conducted a dissection examination. The dissection consisted of using a sharp knife to the stem end, first cut, flower end the second cut, and then a transverse core cut for third. This knife was wiped off between all cuts to prevent dye carryover.

The dissected fruit was then examined visually for evidence of dye penetration and the classified by a three-level index. These includes no uptake, slight or moderate, or he penetration.

This demonstrates--I can't see if you can see the blue dye, but you can see an example of the blue dye being taken in at the stem scar, which is the most vulnerable part of fruit, as an example, and these are our results.

When we had warm fruit and the cold dye, with 178 pieces of fruit we had 7 that had infiltration. This is a 3 percent infiltration rate. We did not see infiltration under other conditions. And I should mention that all of these studies were performed on bot grapefruits as well as oranges. I'm not going to talk about the grapefruits during thi presentation because of time constraints. But the grapefruits were actually more vulnerable to this method than the oranges.

So we conclude from these studies that infiltration of water and dye can occur into intact citrus fruits, that the study is consistent with infiltration studies on other commodities, and this provided suggestive evidence that human pathogens could be internalized into oranges as well.

We wanted then to test the hypothesis that human pathogens can be internalized. So the initial studies were performed the same way by immersing the oranges into aqueous solutions containing pathogens, but because of the very high potential for spurious introduction of these microorganisms into the introduction of the orange or for cross-contamination, we chose a different system.

We used E. coli 0157:H7 that was transformed to express the green fluorescent protein. The reason we chose this organism was because in Peno Fratamico's research it was prov to have a high survival rate in a number of acidic foods, and for that reason we wante be sure that if it did get inside, that we could detect it.

The oranges were California Valencias purchased locally. We did nothing to upset the natural flora on these, so we can say that there was some competing microorganisms.

We grew the organism up, and then as you can see in the upper panel, we applied 10 million or 10^7 cells onto the stem scar, and since we published this information, we now have information on 200 oranges. And I should mention, because the been a number of discussions about the removal of the stem material, we did this for consistency purposes because many of the oranges did not have the button intact when w received the oranges. So we decided for the purpose of laboratory consistency and more rigorous controls that we would take them all off.

In some instances, but not every instance, we included dye. So we have data with and without dye, coinoculated with the microorganisms. And as Dr. Ismail mentioned, the en result was that we took these oranges, put it in the refrigerator for three hours, 4 degrees for three hours, and the internal temperature at the end of this was 11 degree

Okay. To sanitize, we took the stem scar portions, and we immersed it in 80 degree water for one minute, then used a sterile knife to halve the oranges. So we have an inoculated side and an uninoculated side. And then we juiced it with a hand-operated juicer, and I need to be very clear about this. We sequentially juiced inoculated and uninoculated sides in the order of the experimentation. So there was always an uninoculated half that went between two inoculated halves. The juicer was cleaned betw every squeeze.

Okay. Then juice was evaluated and quantified by plating onto two media, BHIA, brain heart infusion agar, as well as Sorbitol MacConkey's, and we consider this a conservat method. There wasn't any attempt to pre-enrich, to wring out all of the live organisms can find. The bottom panel shows that we used detection as well by expression of the g fluorescent protein.

Okay. So out of the 200 oranges, five were positive, which is a 2.5 percent rate. We also looked back at the dye uptake, which was 3 percent, and I think this is an extrem important point. These are the number of oranges, the actual sequential number of the

that were positive. So it was No. 48, 52, 32, 58, and 183, suggesting we did not have laboratory spurious results.

The uptake levels were between 1,400 CFU to 33,000, and this represented a ratio of about 0.1 to 0.01 of the CFU applied. And we did not find E. coli 0157:H7 in any of th controls, which included uninoculated oranges that were spaced in with the inoculated ones.

So we conclude that E. coli 0157:H7 can be internalized into oranges if present on the stem scar under certain conditions, that rigorous controls prove that internalization not an artifact, that the uptake frequency and level of 0157:H7 that is internalized i low, 0.001 to 0.0001 percent; that pathogen and dye uptake frequency in levels are similar, and this suggests to us that it is a reasonable surrogate.

Okay. From this information we wanted to look at whether or not there was a potential for survival and growth. And could I have a time check right now?

MS. JACKSON: You have approximately 13 minutes left.

DR. MILLER: Okay. Thanks.

Our rationale was that the only way that a pathogen has potential to become internalized within an orange, the microorganism will become a potential health threat only if it can survive long enough for consumption. So in this phase of the project, w wanted to evaluate the potential for survival and growth in the fruit using various internalization techniques.

In this case, we used both E. coli 0157:H7 as well as Salmonella Hartford, which was a outbreak strain. We applied 500 cells per orange, and it was inoculated in one instance--as you see in the upper panel, these were injections made into the core thro the stem scar, into the albedo as well as the section or pulp portion. So these were direct injections, and, again, the goal was to look at survival, assuming that internalization could occur.

As you see in the bottom panel, we also tried to simulate wounds by using the tip of a 1-ml pipette tip to bore into the orange at five locations. We looked at two depths, 4 5 millimeters into the albedo and 10 to 11 millimeters into the section portion, and e of the five wounds were then inoculated with one-fifth of the culture. So in both instances, both the direct injections and the inoculation into the simulated wounds, w fractionated our dosing one-fifth to each wound.

These oranges were incubated either at room temperature or 4 degrees for five days. Th oranges were then quartered with a sterile knife and juiced in a Stomacher, and then t juice was plated onto both selective and non-selective media agar using a spiral plate

The first two data columns, which are at 4 degrees C.--and this is E. coli 0157:H7 data; I won't show you the Salmonella because of time--indicates that there was a decl at all anatomical sites when injected or applied into simulated wounds. However, the r data columns at 21 degrees showed there was a less-than-1-log increase in the core injected samples, showed that there was a 2-log increase in section portions that were injected or inoculated within simulated wounds. There was nearly a 1-log increase when bacteria were inoculated at the albedo through a simulated wound, and there was no evidence of the presence of the microorganisms in uninoculated controls.

So for the E. coli data, we conclude that at refrigerated temperatures we saw population decline, but at room temperature the population grew, survived and grew. An did see very similar results with the Salmonella Hartford.

With those data as a backdrop, we wanted to compare how pathogens would survive in the juice, so we expressed juice from fresh oranges that were uninoculated, and then inoculated with either E. coli 0157:H7 or Salmonella Hartford at approximately 10,000

CFU/ml. This was placed either at 4 degrees or 21 degrees, and then aliquots were withdrawn daily for three days, plated, and incubated.

These are the results. The data on 4 degrees for both organisms are presented on the left. At 4 degrees there was no change in the levels of either E. coli or Salmonella, the uninoculated background flora, which is the third data column, total aerobic plate count in the uninoculated controls grew by over 1 log within the three days. The three data columns on the right are at 21 degrees, and there was a 1-log decrease in E. coli Salmonella Hartford. And here the background microflora grew 2 logs on the controls, j the native background flora.

It is our conclusion for this segment of the research that pathogens survived at 4 degrees, but populations level declined at 21, that results were similar for E. coli 0157:H7 in salmonella, and that the native microflora grew in un-inoculated controls.

The ability of these pathogens to grow in pathian oranges, but not in juice, may resul from the micro environments that can exist in intact oranges.

Compartmentalization of acidic juice within vesicles may allow for an environment within the fruit that is more conducive to growth.

So, wrapping it all up, public comments suggested that pathogens were not confined to orange surfaces. Therefore, we conducted a literature review that gave us some suggest evidence that it is a possibility that internalization can occur. FDA performed a seri of studies, including a dye uptake study, which we saw internalization. We conducted pathogen studies on oranges. We saw infiltration; in some cases, survival and growth. conducted a pathogen study in orange juice, and we saw survival or inactivation.

The pathogen study was in agreement with the dye uptake study in that about 3 percent of the oranges took up dye or pathogens, and this suggested that dye uptake is a reasonable surrogate for the pathogen studies.

This study showing pathogen infiltration growth and survival is also consistent with previous research using other fruit commodities.

So, in conclusion, this study has shown potential for infiltration, survival, and growth of human pathogens in oranges based upon laboratory experimentation.

There is no doubt some arguments that can be raised about the unrealistic conditions a internalization does not happen. I would respond by saying that we chose a set of conditions, a single set. Now the onus is to determine the range where these hazardous conditions exist. Only then will we be able to determine the safety of the prevailing industry practices.

You can also argue that internalization does not occur and that surface treatments are sufficient. To this, I would say that we need to consider the whole package. We need t realize that there are various contamination sources affecting citrus and juice, and t is need to treat this processed product from grove to glass in a manner that inactivat all pathogens.

Thus, while surface treatments may inactivate surface contamination, it will not kill internal pathogens, nor those induced during juice manufacturing, shipping, or holding

In the current study, we focus only on one factor, the potential for internal contamination. Given the other contamination sources, it can be argued that surface treatments are insufficient regardless if internalization occurs rarely or frequently. Instead, treatments need to be delivered in an efficacious manner and at a stage of processing that assures intimate contact with all pathogens regardless of the source.

Thank you for your attention.

[Applause.]

MS. OLIVER: Thank you.

At this point, I would like to open it up for questions from the committee for all of the presenters on research, which includes Dr. Ismail, Dr. Pao, Dr. Parish, George Strobos, and Dr. Miller.

Does the committee have any questions or clarifications for that group of people?

MR. TOMPKIN: This is Bruce Tompkin.

In the material that was handed out, the question with regard to internalization is on and growth is another. In the data that was provided in the handout, in this notebook, there was evidence of growth within the orange or at the inoculation site. Yet, there no evidence for growth in juice when juice has been inoculated and held at either 4 or Centigrade.

I would like to have someone help me with that.

MS. OLIVER: Dr. Miller?

DR. MILLER: We cannot look at intact fruit the same way we do as juice. When we have a intact fruit, we have a very elaborate anatomical structure, a series of anatomical structures that confines the juice into vesicles. Once this is lost through the juicin process, the pH becomes much more uniform. So, in the fruit, there is much more compartmentalization of the harsh environment.

MS. OLIVER: Dr. Morales?

DR. MORALES: This is a question for Dr. Strobos, more for clarification than anything else.

In the very first table you presented on batches tested where you had over 17,000, I was curious. Under that column, you had a parenthetical pathogen in those. What does t mean in that column?

DR. STROBOS: Excuse me. Which column?

DR. MORALES: It was that very first table that you presented where you had over 17,000

batches that you had tested for E. coli and salmonella.

DR. STROBOS: Right.

DR. MORALES: Under batches tested, you had the number of batches tested by individual companies, and on some of them, you had a parenthetical of E. coli or salmonella.

DR. STROBOS: Oh, right. That is because for two of the companies, all batches were tested for both E. coli and salmonella. For the other two companies, for which those l are broken out separately, some batches were tested only for salmonella and some batch were tested for both E. coli and salmonella. So I separated those out. The larger number--I do not have it in front of me right now, but there are two companies for whi those lines are broken out, and the larger number represents the total number of tests believe the larger number is in each circumstance for salmonella.

Yes. For instance, under California Day-Fresh, you have 337 batches that were tested for E. coli and 81 batches that were tested for salmonella. So 81 batches were tested both E. Coli and salmonella, and then the residual, which is like 250-some, were teste only for E. Coli.

In the other example from Perricone, you basically get the same circumstances, where 6,379 batches were tested for E. coli and then 598 were tested for salmonella and E. c

Remember that California Day-Fresh and Perricone plants have basically voluntarily adopted the mandatory HACCP program that exists in Florida. So they have been coming online more gradually. Whereas, the fresh juice company in Orchid Island have basicall had this system in place for 3-1/2 years, and the Florida system has been mandatory in Florida.

So, in the Florida companies, the Fresh Juice Company and the Orchid Island Company, each batch has been tested since February 1996 for both salmonella and E. coli, human pathogens.

DR. MORALES: I think that sort of answers another question I had. I was curious about what the time period was over which these batches were tested. So, for the Florida companies, it represents a 3-year period, and for the two California companies--

DR. STROBOS: Yes. It depends on when the particular company began instituting the test

DR. MORALES: I have a couple of other questions on that table.

What does a batch represent in that data, and where was the testing of these batches done for the pathogens?

The last question I have, how were your samples tested that went for testing?

DR. STROBOS: Okay. Is Dan King here? He is the guy who is actually responsible for doing that.

Batches, of course, represent once a lot of oranges are juiced. Then that particular batch is tested, but let me let Dan address it.

DR. KING: Just quickly, there are several different sizes of batches that may be included within the data. A typical batch size would be in the range of 3,000 gallons. have batches ranging up to 5- and 7,000 gallons.

The mathematics on this indicate about 150,000 fruit per batch is being represented here in the testing. In terms of when it is tested, at Fresh Juice Company, we test bo at the immediate extraction level that is in the tankage that follows extraction, and also test the finished product. The other plants test the finished product, and also s test the tank product as well.

Is there a third?

DR. MORALES: How were your samples selected for testing?

DR. KING: Samples are typically taken from either finished product or tank in 100-milliliter samples, of which a 25-milliliter sample is then taken to a pre-enrichm of 1-to-9 solution in peptone broth.

In the tank situation, the juice is being stirred consistently so that we are getting an even distribution. In the finished product, we shake it up to be sure we are gettin distribution.

MS. OLIVER: Art?

DR. LIANG: Art Liang, CDC.

Is this a 100-percent sample of your batches?

DR. STROBOS: Yes, it is 100 percent.

DR. LIANG: Actually, my main question was for Dr. Parish, about the issue of submersion.

So Florida is different from California. In California, 30 percent of their oranges gets immersed, and in Florida, no oranges get immersed. Is that correct?

DR. PARISH: In Florida, to my knowledge, no oranges are immersed, and I am fairly knowledgeable about the fresh-squeezed operations.

Let me point out that the vast majority of the oranges in Florida that go into fresh juice are field-run oranges; that is, they do not go through a packing house line. The are simply harvested and brought to the processing plant.

For stored oranges, some oranges are stored under cold storage conditions, and those oranges typically are run through a packing house line so that they are waxed, put int cold storage. Then, at some later date, they are brought out, re-graded, and re-washed

DR. LIANG: But as far as you know, those packing houses do not immerse their oranges a any part of the line?

DR. PARISH: That would be Dr. Ismail's bailiwick. To my knowledge, no packing houses immerse oranges.

DR. STROBOS: Let me just make clear because we have to have some California companies. Again, we are asking for the same kind of mandatory HACCP program to be applicable in California that is currently in Florida, and the companies that we are talking about h in California do not use immersed fruit either.

MS. OLIVER: Larry Beuchat?

DR. BEUCHAT: I would ask all three of the presenters the same question. Was there any adaptation of the cells that you used, whether it be salmonella or E. coli, or E. coli 0157:H7 prior to inoculating the fruit? In other words, what was the condition of thos cells at the time you harvested them to inoculate on the fruit?

DR. MILLER: Our cells were grown overnight in BHI. We add a little glucose to stress them, and they were stationary-phase cells.

DR. BEUCHAT: Do you happen to remember the pH at the time you collected the cells?

DR. MILLER: I do not have that information right at the tip of my fingertips.

DR. PARISH: Larry, in the studies that we have conducted, none of our cells are adapte to acid conditions.

I have published research in the past on acid-adapted salmonella, and we have shown that salmonella adapted to acid conditions can survive in orange juice for very extend periods of time under refrigeration that is in the juice itself.

DR. PAO: For one part of my study, we submerged fruit in E. coli, generic E. coli culture, for commercial juice processing testing, and that culture was cultivated in nutrient broth for 24 hours before inoculation.

DR. BEUCHAT: Thank you.

DR. STROBOS: I think it is the better part of valor when you do not know the answer to say you do not know the answer. We could certainly get back to you on the growth conditions and the adaptation of the organisms in our studies.

MS. OLIVER: Peggy?

DR. NEILL: I have a question for Jur Strobos.

I apologize if I have missed this, but I have looked repeatedly through the documents in your section, and I cannot locate a description of the test methodology. Could you clarify that for us, and could you also indicate what the lower limit of detection is both E. coli 0157:H7 and salmonella using that methodology?

DR. STROBOS: Yes. The methodology is not in there. Sorry about that.

The methodology used for the 0157:H7, I just had someone e-mail that to me, and it is AOAC Official Method 996.09. It is also then apparently cultured out. That, of course, take a longer period of time, but that is the method used. I cannot really provide a w lot of detail about that method.

The method for salmonella is apparently going to get Official Method status in Februar 2000. It is AOAC performance test. It is Certificate No. 971001, and my understanding this is the test method that FDA recommended for our use.

DR. NEILL: Again, in the same vein, can you tell us what the time would have been from collection of sample to analyses?

DR. KING: If I may, we used--

MS. OLIVER: Can you please identify yourself for the record?

DR. KING: I'm sorry. I am Dr. Dan King. I am the quality assurance director for Saratoga Beverage Group.

We collect the sample from tankage or from finished packaged goods, and within an hour we have put that material into a pre-enrichment peptone broth.

In 18 hours, we can use the VIP method for 0157:H7, using an immuno-precipitant. In 16 hours, we remove the material from the broth doing the salmonella test. It is then tak through the Tecra unique process, again, using a sandwich method technique to trap and then identify the presence of salmonella.

DR. NEILL: Last question for Jur Strobos. In the interest of transparency, a number of the presenters have been very helpful in volunteering their background. I notice you a listed as "Esquire" on the agenda and "M.D." on the letterhead.

DR. STROBOS: Yes. Both of those are accurate. I am a physician. It is medicine, though not microbiology. I trained in medicine at the University of Chicago, and I got my J.D the University of Pennsylvania.

MS. OLIVER: Dane?

MR. BERNARD: Thank you. Dane Bernard, NFPA.

Question for Dr. Pao. A lot of information is there, and it is difficult for me to kee up. There was something in your study where you showed a 5.4-log reduction. Is that wh you inoculated the surface with 10 to the 7? Was that on the stem scar? Could you revi that for me real quick?

DR. PAO: I think you are talking about the last part of my presentation. We inoculate the fruit into a cultural bacteria, E. coli culture, 10 to the 9, in the culture. The fruit after immersion and air-dry, the surface comes to 4.5 log, and the massive rated fruits used was also 5.4. So the first bar I showed in my presentation indicates massi rated juice content, which I believe is representing the total inoculation.

MR. BERNARD: You did not clean the fruit.

DR. PAO: No.

MR. BERNARD: This was not a challenge of a washing procedure at all.

DR. PAO: No. This is single to demonstrate juice extraction can reduce near 2 log, how water treatment in juice extraction can reduce more than 5-log reduction.

MR. BERNARD: As my colleagues on the committee know, I am easily confused. So forgive me if I have to go back and ask you again because I am not understanding.

You dip the orange in a bath that had 10 to the 9. You allowed it to dry.

DR. PAO: Yes.

MR. BERNARD: Then all you did was juice the orange, extract the orange.

DR. PAO: I have four different bars. The second bar indicates exactly what you mentioned, juice extraction, those inoculated fruit, and that juice extraction process gave us near 2-log reduction.

MR. BERNARD: Is that with a commercial juice extraction?

DR. PAO: Yes.

The third and fourth bar did not show on the chart because we did not recover anything higher than 1 cell per mil. We were not able to recover.

MR. BERNARD: Nothing there.

DR. PAO: Right, after hot water treatment.

MR. BERNARD: After the hot water treatment.

You did not use the commercial scrubbing protocol in that study?

DR. PAO: No.

MR. BERNARD: But if you had contaminant on the surface and you did nothing to the orange but extract the juice, we did have microorganisms in the juice, inoculum in the juice?

DR. PAO: Could you say it again?

MR. BERNARD: I will try. You dipped the oranges. We had 10 to the 9 on the orange.

DR. PAO: 10 to the 9 in the--on surface, we had 10 to the 5.4.

MR. BERNARD: Okay. With 10 to the 5.4 on the surface of the orange, we put it in a commercial extractor. Was this an FMC?

DR. PAO: No. This was another company.

MR. BERNARD: Do they work similarly?

DR. PAO: We have done tests and compared differences, not directly compare, but test the different kinds. We got similar results.

MR. BERNARD: Okay. So we have how much on the surface of the orange, 5.4?

DR. PAO: Yes.

MR. BERNARD: And we extract that. How much in the juice?

DR. PAO: About 3.5.

MR. BERNARD: Okay. So we did have some of your inoculum in the juice.

DR. PAO: Yes. That is a result in any washing--

MR. BERNARD: I understand.

DR. PAO: --and hot water treatment.

MR. BERNARD: I just wanted to be clear on what those results were. Thank you very much

This is in some of the material that Dr. Strobos submitted. There was a HACCP plan included in here, and if I read this correctly, this has to do with the washing step. are talking about a minimum strength of 200 parts per million of chlorine, and we are doing checks on that every 4 hours. It says if the minimum is not found, the line is stopped and starts again only after the minimum strength requirements are met.

Is there anything that the firm would do with the fruit that may have been processed with less than 200 parts per million chlorine?

DR. STROBOS: What you have is the plan that we submitted to this committee, 2 years ago. My understanding is that this process is now continuous. I am not 100-percent sur but I can get back to you in terms of the evaluation of the parts per million.

Again, I do not have the specific individuals in charge of that plan here right now.

MR. BERNARD: Okay. We can talk about that later.

My point is--and I guess in a larger context, we have heard some very good presentations, but they are based on a few companies that appear to be doing exemplary work. My overall concern is how does this committee address to FDA when it comes time say something in relation to all of this. What kind of recommendation can we make to F that says that there will not be an outbreak in 2 weeks or 3 weeks or 3 months if we accept that, okay, it is doubtful that we have got internalization? I do not think I h seen conclusive evidence one way or the other so far in any of these presentations, bu your assertion is that the problem has been a failure in GMPs, how do we address that we have got information from people doing exemplary work? How do we make a recommendat to satisfy Laurie Girand that we do not have a problem next week, next month, or next year?

DR. STROBOS: Right. Well, I think the answer--maybe I should have Dr. Ismail answer that. These four companies have been operating pretty much independently, and have all developed their programs pretty much independently. We only came together in September the purpose of this particular meeting.

You can talk about them as being exemplary, but I think that is actually a wrong concept. I think you have to say to yourself that 3-1/2 years ago, Florida put in a control system that applies to all juicing operations that export from Florida basical or that reach a certain minimum, and all of those juicing systems operate the same. I think the four companies that are represented here happen to be the largest of the companies that perform in that way and have communicated together, but I do believe th

later in the public comment period, there will be individuals from some of the other companies that also comply with the Florida HACCP programs that have had similar resul I think the Florida Department of Agriculture could certainly speak to the fact that t system they have put in place there is not rocket science and it is something that ha been working in the State of Florida for all the companies to whom it applies for 3-1/

years.

That is what I am asking you to do. I am asking you to look at an existing regulatory program that has been in place, that has a lot of details to it, and we just represent four companies that have complied with that program.

MS. OLIVER: Cathy Donnelly.

I am going to take questions for 5 more minutes. I know we are running over, but I kno there are still a lot more questions. So I will try to do 5 more minutes for questions

MS. DONNELLY: I am not sure who to direct this question to. Perhaps Dr. Miller could answer it, or Dr. Parish.

I am confused about the specific regulatory methods that are used to target detection of specific pathogens, E. coli 0157, as well as salmonella, in orange juice, A, if the are specific regulatory methods, and then, B, how might those methods differ from some the methods we have heard today, the CDC method, et cetera. Could someone comment on t

DR. MILLER: I will take a stab at it, but there are certainly better--

MS. OLIVER: Art, if you could identify yourself for the record, please.

DR. MILLER: Art Miller.

Particularly for the incidence of orange juice, it is fundamentally for salmonella, th band method with certain modifications. The traditional band method analysis for pre-enrichment is to use lactose broth, and because of our inability to detect salmone from some previous outbreaks, we have just conducted some studies that are in the fina stage of preparation, and we are recommending now to use universal pre-enrichment whic was developed by the ARS Group in Athens, Georgia.

This was first recommended by CDC. We have done side-by-side comparisons, and there is really a dramatic difference between these two methods, universal pre-enrichment versu lactose broth. Just numbers that come to mind from some of the data I have seen, looki at a variety of salmonella strains at a host of levels, at least in the studies that w have done, the recovery rate for the traditional method using lactose was about 44 percent. I do not have the exact data with me, but this is low levels, wide range, goi down to about .03, or thereabouts, organisms per mil.

So, for lactose, it was a 44-percent recovery. For universal pre-enrichment, it was over 80 percent. So we just about doubled our recovery by that one modification.

Is that your question, Cathy?

MS. DONNELLY: Yes.

So you will be recommending the use of universal?

DR. MILLER: Right.

This was presented at the recent food micro conference in the Netherlands, and that manuscript is in preparation right now, but certainly people that we talk to, we are recommending the change in that procedure.

MS. DONNELLY: Then when we hear reference to use of a CDC method for assuring that there has been compliance with HACCP for GMPs, we are talking about the universal pre-enrichment.

DR. MILLER: I am not going to speak for CDC. There are representatives here. Maybe Swami will take a stab at that.

I know they have tried a number of methods, and he will have to define what he is calling the CDC method.

DR. SWAMINATHAN: What is being referred to as a CDC method is the one that yielded a positive sample from the first investigation at the outbreak. Several laboratories attempted to isolate the organism from the orange juice, and this method was the only at that time that was successful.

We have distributed the method to several of the State agricultural and public health laboratories and, of course, shared it with FDA and would be happy to share it with yo do not keep those temperatures and incubation times in my brain. I just do not have th storage capacity.

DR. PARISH: I am Mickey Parish, University of Florida.

I am not sure I can add anything to that.

After the 1995 outbreak, I think which is the one you are referring to in Florida, we worked closely with the diarrhea lab at CDC, recognizing initially that we were having difficulties isolating salmonella from the samples and that the modification was necessary.

It is my understanding that the modified BAM method that Art was referring to includes some of those modifications and that it is more sensitive at this time.

MS. OLIVER: We have time for one more questions.

Nancy?

MS. NAGLE: My question was more back to Jur Strobos.

We talk a lot about this inspection process that is being used to weed out these damaged fruit. How exactly do those work in the plants? I am looking at these pictures that we have seen, and it is huge numbers of fruit going by on a belt. Is there a posi movement that the fruit has to be moved physically from one layer to another so that someone is actually touching it and handling it, or is there just like a random--

DR. STROBOS: I am going to ask someone from Orchid Island.

I have seen the facility at the Fresh Juice Company, and it is on rollers and the frui is moving forward, but different from the pictures that John showed a little earlier, the Fresh Juice Company, the roller is sort of narrow. There is actually a time point where only one orange is sort of rolling past a group of inspectors or actually where USDA inspector is. It is one orange per path as it goes through.

It is fairly amazing that you can process the number of oranges that they do, but they do have a lot of inspectors and examiners. I would suggest frankly that these people a pretty experienced. I am not convinced that FDA's look at their oranges was any differ or any better than what is occurring in the plant. I do not know whether that answers question or not.

MS. NAGLE: I guess the question is that we are looking at saying this inspection is a critical control point. How do you know that each one--that the person did not blink a that one went by and was not looking at it? In several other industries, there is an actual physical movement by the inspector. They pick up a tomato or a head of lettuce, it moves from this belt to this belt. The only way it gets there is by a person pickin up. The person may not be looking at it, but there is at least another form of guarant

DR. KING: That is what occurs in the--

MS. OLIVER: Can you identify yourself, please?

DR. KING: I'm sorry. Dr. Dan King from Saratoga Beverage Group. That occurs in the citrus plant as well. In our plant, we have two facilities, two areas of facility wher have eight graders, four on each side of the run of fruit coming by, who are physicall handling the pieces of fruit as they come by. They are visually inspecting, looking fo default. They are also physically feeling for softness or unacceptable fruit in that fashion.

MS. NAGLE: Then it goes to a different belt?

DR. KING: Yes.

The first process takes place as the fruit is unloaded. It goes through a first-washin stage for sanitization. It then goes to a State lab evaluation, which Jur referred to, then it goes to a storage bin.

When we go to actually process, to extract the juice, those fruit again are run throug a belt system, passed a second set of brushes and washes and sanitization, and another of graders.

MS. NAGLE: My question is still that these graders--if the grader was not there, would the fruit end up at the extractor anyway? If the grader disappeared, would the fruit e up in the extractor?

DR. KING: Yes.

MS. NAGLE: That is different than the process I am describing. Whereas, if the grader is not there, the fruit does not go anywhere because it is another belt where the pers picks it up and moves it.

DR. KING: But if the graders are not there, the process is stopped in our situation. There is no further movement of the fruit unless we have the proper number of graders place.

MS. NAGLE: Okay. Well, fine.

MS. OLIVER: Thank you very much.

We are going to break for lunch now for one hour, but before that, I just want to tell you this. My staff gave me a note. We are going to ask to have the doors locked to the room over lunch time while we are at lunch, and we are going to ask to have a coat rac brought in because our intern's coat has apparently been borrowed by someone when it w next door in the coat room. So, hopefully, all of your coats will be there. We will be back easier to try to open up the room, but we will be back at five of.

[Whereupon, at 12:51 p.m., a luncheon recess was taken, to reconvene at 1:59 p.m., thi same day.]

A F T E R N O O N S E S S I O N

[1:59 p.m]

MS. OLIVER: Good afternoon. I'd like to get started, please.

Our first presenter this afternoon is Dr. Peter Slade, and he's co-chair of the Food Safety and HACCP at the National Center for Food Safety and Technology at the Illinois Institute of Technology. He's talking about hazard analysis and operability studies, failure mode effects analysis. And, Peter, I'd like to tell you we've been keeping

everybody on time so far, so if you haven't been here, just to let you know. We are be time, but we've been trying to keep it as close as we can. So that's your introduction

DR. SLADE: Okay. Thank you.

I'd like to talk about risk and hazard analysis. Before I start, I just want to--a lot of terms were mentioned this morning, and I just want everybody to get their bearings.

These slides are actually from a presentation I gave five years ago in 1994 at an IFT meeting, and not much has changed since then, but it will help you get your bearings, said.

Risk assessment is divided into these categories here. And I won't go through all the definitions. And this leads us to risk management and risk communication under the umbrella of risk analysis.

Next please. Traditionally, and I term this epidemiological risk analysis, risk assessment rather. We have these various factors have some bearing on the final risk characterization, risk management.

When I gave this presentation five years ago my entire angle was: well, this is very nice. It tells us which bacteria are of interest, which foods they may well be found i I'm more interested in the risk involved with processing operations, and this is -- ve little is known about this area, so I presented an alternative model.

Next, please. It looks very similar, but if you see, we have epidemiology still up here. Everything that comes from that traditional risk, risk assessment is includes. I added HACCP, hazard analysis in HACCP. This thing I'm going to talk about today, HAZOP to identify hazards, in the process sector, you know, we're interested in specs and li and our process controls. Again, HACCP has some bearing on this. Survival and growth o the pathogens concerned can be looked at in mathematical models and equations to characterize the risk. The risk of failure of a process in operation is where we're leading here, and how we manage those risks.

So I ended that presentation all those years ago with looking to a marriage of this traditional epidemiological risk assessment, which there's a lot of work being done in this area still, and trying to develop this whole area of process risk assessment.

Next, please. And the main reason we're here today, of course, is this is--again, I won't explain too much--but when these unfortunate events occur, the way they're characterized in process leads to a ripple effect with the victims, the companies involved, the industry, and even other industries beyond that directly involved, and t are some of the impacts that we see, consumer response, regulatory constraints, litigation, financial losses. It was true then. It's true today very much so.

So the full title of my presentation--I've expanded it from the original--is "Risk and Hazard Analysis in HACCP, Potential Applications for HAZOPS, FMEA and FTA", and HAZOPS is Hazard Analysis Operability Studies, FMEA, F-M-E-A, Failure Modes Effect Analysis. When you have the C in there, that's criticality, and the Fault Tree Analysi FTA. That's just an explanation of those abbreviations. FTA has a sister right at the bottom there, Event Tree Analysis. And I'll briefly explain how we can examine cause a consequence, using both.

This is an overview of my presentation today, a brief description of risks and hazards Some needs that have been identified within the juice industry, what's wrong with HACC Why do we need these other hazard assessment tools? Some discussion on failure and suc and reliability of process operations, general safety program objectives, in depth analysis--well, not so in depth, but some exposure to these analysis tools, and then h do these relate to HACCP with respect to the juice industry?

And I'm reminded by Dr. Ismail's comments there regarding the truck of cow manure and

the oranges here, if anything can go wrong, it will go wrong, Murphy's Law.

So to get our bearing on the risks and hazards, these are two definitions that I found in the literature. There are others, but generally this covers the ground for us. And some--an overview of a safety analysis. Usually is conducted in this manner: review of historical data, study ways in which the product has been used and abused, and you'd probably be familiar with these as part of the 5 steps leading up to the 7-part--7 principles of HACCP. And then the new part, marrying these two elements with the risk analysis, assess the risk the damage will actually do, either through a failure of a component or a process, and the risk of having a product contain the hazard, as the consumer sees it. And then somehow quantifying exposure and assessing the severity of hazard.

HAZOPS, FMEA, Fault Tree Analysis, those kinds of techniques are used very much in other processing industries, and I've given some examples here. Petrochemical, aeronautical, particularly nuclear energy. The military uses these techniques to a gre

extent to evaluate their equipment. Medical devices, FDA applies FMEA in their evaluat of medical devices. And the automotive industry, quality is job number 1 at Ford, and not just TQM, but a lot of these principles apply in the automotive industry.

Staying on that theme, Henry Ford said, "Thinking is the hardest work there is, which is probably why so few engage in it." Why I put this slide up is my talk today is very short on specifics relating to the juice industry, but hopefully there will be some "ah-hahs" out there that you can grab and relate them to how you're involved in these particular questions.

This come out of a proposed regulation from a couple of years back, and identification of the hazards, and you're all familiar with those, of course. But there's also a part the proposed reg that describe the process as "must determine the likelihood of a hazards occurrence", and this has bearing, obviously, on the main part of my talk.

Future needs were identified, and again, I won't go over those. We have short time. Bu some of the practices that were identified. This actually came from a 1997 report in t apple juice industry, but I think some of the points have bearing on the citrus fruit juice industry as well, and again, more steps were described there. But at the bottom you'll see further risk reductions. Here we again see the term "risk" with some idea that a risk assessment must be done on these products.

So what's wrong with HACCP? Well, nothing. I'm not proposing to you that we replace HACCP. All these systems I'm going to describe are ways to augment current traditional conventional thinking in HACCP. HACCP works when it's designed and executed properly, I think Don Zync [ph.] from Nestle, has mentioned in more than one occasion that this very much the case and people lose sight of this. But having said that, in traditional HACCP, just defining why hazards should be included in the plan is very often difficul and subjective. Fortunately, we now say should the hazard be included in the plan as asking--rather than asking the significance of that particular hazard. That's a very difficult thing to do even with a team of experts.

CCP determination is based on this subjective evaluation of acceptable level, which ma be another criticism. Critical limits are usually all or nothing. We know in the food processing industry there's a lot of gray areas. What if different combinations of tim temperature, whatever, as opposed to the actual critical limits stated occur, what the Well, HACCP really doesn't accommodate this too well. HACCP, it's general application process, that is, manufacturing process oriented, as opposed to system focus. Unfortunately, there's a lot to do in distribution HACCP. I've worked on that in the p I'm working on something on packaging HACCP right now. So there's lots outside of our traditional focus that needs to be addressed.

I came across this in my reading Military Standard 882 from 1969, and interesting enough, we hear a lot about Pillsbury--NASA started HACCP in 1971, but I see some

components here that could well be HACCP terminology from 1999. But you see the second bullet there: "Hazards associated with a product should be identified, eliminated or controlled to an acceptable level." So maybe this after all is the precursor of modern-day HACCP.

At the bottom there you'll see that term "risk" again came up even 30 years ago, when new materials--and again, think of the juice situation, when you buy new materials from a new supplier, perhaps, and how those risks have to be analyzed and hopefully minimized.

We talk a lot about corrective actions. Well, the NACMCF document does describe what sort of things need to be considered, and I found this is an article by Duran [ph.] regarding quality techniques, but these play equally well to the food safety situation

Again, the proposal describes a one in 10^{-5} chance of getting sick from consumption, individuals' annual risk of one in 10^{5}. This table I think is derived from British data, but you can see the sort of risk categories that have been proposed. Up here is the risk of dying in a car accident in the UK, which is far too h of course, and down here an acceptable risk is something like lightning strike. Everyb in this room stands about a 1 in 10 million chance of being killed by lightning in any particular year. So, again, put in that 10^{-5} criteria into perspective. Evaluating against other risks is very important.

So getting into the main part of my presentation today and a discussion of some of these hazard analysis techniques. The first one is HAZOPS, Hazard Analysis Operability Studies. This is a very systematic approach to evaluating failures of equipment primar so it's not good for a process, it's not good for a system in its entirety, but certai for equipment it's very useful. It's driven by use of these guide words. See, each ste evaluated step by step, and a simple list of guide words are applied. If you have a process, say it's a temperature, what happens if there's none, more, less, a reversal temperature from going up to going down, for example? Each step is evaluated like that and then the cause and its consequences are evaluated to be realistic or unrealistic. they're unrealistic, they stop and you move on to the next guide word. If they're realistic, the consequences are evaluated as to whether they're going to be trivial or hazardous. And if they're hazardous, you record the hazard and determine an action pla and then move on. So a systematic approach, but keep in mind that it's very much equipment-focused.

Here's another way of looking at it, from the unit operation, which I've taken the liberty of calling a CCP. Again, this may be a critical piece of equipment where you'v actually determined to be CCP through a traditional HACCP approach, then how you apply those guide words parameters causes consequence, safeguards, actions.

Much like one of the first slides--overheads I showed from my original presentation, the risk of the operation failure leads various undesirable events, potential recall, regulatory action, negative public opinion. It kind of gets worse as you go down the l of course. Negative public opinion, legal and financial liability, increased cost of operation, lost market share and potential bankruptcy, and a plant shutdown.

So I just want to show you exactly what a system like this would look like. I've mentioned the guide words. You know, this is typical of the sort of list you see. Ther may be 5, 6, 7 guide words, no more than that.

Parameters. I mentioned temperature, pressure, time, flow rate. All of these may be critical at a CCP in a food processing operation.

Causes can be identified. These are very specific equipment failures, failed controls, corrosion, poor maintenance, operator error. I'll be coming back to human reliability later on.

What are the consequences? Equipment damage is okay, but if we deviate from a critical

limit or we have non-conformance to specification, we're obviously in breach of the HA criteria here, and we may well lead to regulatory non-compliance. Release of product, course, would be catastrophic.

How do we--what are the safeguards? Inspection and detection. This could be end-produc testing. It could be in-process testing, testing and calibration of this critical equipment. Various fail-safe systems. We heard about the alarms this morning, for exam And procedures and training, documented procedures and thorough and extensive training employees. The actions that have to be taken then. Redundant systems, this ties in wit the alarms. Design modifications, new equipment, call on disposition, and yet more procedures and training.

So moving on to Failure Mode Effects Analysis, and I mentioned its sister, Failure Mod Effects Criticality Analysis. But starting with the basic approach, what is a failure mode? A failure mode is a manner in which a product does not meet customer requirement And then we look at the effects of this failure, and that is the study of the effects the failure on its fit-for-usefulness or its intended purpose.

FMEA has a lot in common with a traditional HACCP approach. It's very--it goes beyond equipment to an actual process examination, so it's a very systematic approach to analyzing failures of a process. So if you like, this one truly is a cousin of HACCP. There are three main steps. You list the failure modes for the particular design for e the effect on other components, the process or the overall system is assessed, includi its likelihood of occurrence, its severity, and if you're doing the criticality analys you also have the detectability. So traditional FMEA includes likelihood of occurrence that's the probability of this thing happening, as well as its severity. So risk, if y like, is probability that's occurrence; severity is also called consequence. So we hav traditional risk/consequence type of matrix. We had a third dimension here with detectability. And then corrective action, various plans are written and corrective ac is taken or proposed.

So here we see it. It's very much bottom up. You have these various unit operations, which are analyzed by this very systematic approach, and I'll show you how a chart is- table is generated. This may be assembly of these components from the unit operation. may be a sub-process such as packaging, and if it's up here, you have the overall, hopefully, successful process.

Two main types of FMEA are design, used primarily by the design-responsible team, and process FMEA, used primarily by the manufacturing-responsible team. So both are import with respect to safety. Hopefully you can eliminate a lot of potential hazards or risk via a good design, but if you don't catch them all there, certainly the process should minimize the effects of those hazards.

So a design FMEA will help assure the design-related failure modes and effects that ar being addressed. It identifies actions to reduce, eliminate the failures due to the design, identifies associated causes and mechanisms, aids in the internal planning and test development, and tracks and documents risk reviews and actions, is a useful refer document for future work.

Process FMEA has much in common as design FMEA. It helps assure that production-relate failure modes and effects have been addressed, identifies actions to reduce or elimina identifies associated cause and mechanisms, but the last two are different here. It identifies the process variable, so that if controlled, can reduce the occurrence or improve the detection of failure conditions. And it also helps prioritize corrective actions. This prioritization is very important.

So a chart is put together much like we generate a table in HACCP. The purpose of the particular process, the step or the unit operation is described, potential failure mod are identified. The effects of the failure are described, and the SO there refers to t severity and the occurrence of those effects. The potential causes of failure are identified, and the occurrence, O, is identified. Current process controls are

recommended, and these are generally considered in that detection mode, D for detectio

This generates a number. If we multiply those probabilities, so you can start with a scale of 1 through 10 for each of those items, S, O and D, and so have a three-dimensi model, if you like, that can be developed. It gives us our risk priority number there, risk--RPN_0 is the risk priority number from the process that is out of control.

Once we make recommended actions with responsible people identified with a completion date, then we can monitor the action results. We apply the equation again, S, O, D, on we put some corrective actions in place, and we get a new risk priority number, RPN_1. So this just shows you how to generate that risk priority number. The importance here different from HACCP is that this technique allows some probability to be given, some number that can be put against these failures, so we can actually evaluate the failure based on this number and see how we improve by making corrective actions. HACCP doesn' allow this.

A few caveats here. The risk priority number is used as a guide to rank concerns. When it's applied in that sense of criticality, the lower the better. It's like a golf scor The lower the number, if you have a 10 by 10 by 10, we can score 1,000, we want to be low as possible out of 1,000.

Do not set threshold values. This skews the team's judgment. These values aren't legally binding anyway, so if push comes to shove and you find yourself in a difficult situation, they're not worth much legally. But very importantly when that S score is h special attention has to be given to the severity score.

So some of the recommended actions that are generated by that new score, we can reduce the severity scoring by design revision. We can reduce the occurrence by removal of control of the cause or an underlying mechanism, or we can reduce detection by increas invalidation verification activities. So this use of the term "detection" here, general thinking, conventional wisdom tells in HACCP we don't rely too much on in-prod testing or any kind of detection. This type of detection is to -- a process failure detection; it's not so much, yes, we have the pathogen in the final product, so it's m to do with detecting an out-of-control process.

Moving on to the last of the triad here, Fault Tree Analysis. Fault Tree Analysis is a way of looking at failures of an entire system, a very useful technique. It allows a l of statistics to be applied. It gives us a good number of probability that we're going have a risk. It differs from FMEA in 3 main respects. Fault Tree Analysis studies only rely on negative outcomes. FMEA studies all potential modes of failure. Fault Tree Analysis can analyze situations in which negative outcome will not occur unless severa sub-events first occur.

The great beauty of Fault Tree Analysis is it involves using and/or differentiating terms that allow some Boolean [ph.] equations to be applied, so you can have an or ter that shifts the probability calculations to one side or the other, and likewise, you c include the end terms to include a lot of sub-events, which all give you a more accura figure on the likely outcomes.

Fault Tree Analysis shows explicit interactions between events. Three main steps, much like FMEA, a list of failure modes is developed, and each is analyzed. The root cause each is determined, and then corrective actions are proposed.

So it's a 7 step process. Don't want to draw any parallels to the 7 principles of HACC here, but firstly, the system is defined. A simple block diagram is elaborated. The to event is defined. This is a top-down process, by the way, as opposed to FMEA, which is bottom-up. So we start with that unfortunate or undesired event as the top event. The Fault Tree is constructed. It's analyzed. Recommended corrective actions are proposed, then we document the analysis and its result.

So I've given a simple example here. It just shows how we can use these--all dates in

this case. I don't have any end dates. I haven't used the correct symbols either, but can generally see the flow. Top-down, we start with the failure of the lights. It coul caused by a number of different things, the power goes out, the bulb or the fuse. Here have the occurrence, annual occurrence of each of these things happening, and then on fuse, for example, we have another couple of causes of the fuse going out, and again, these have a probability assigned also. So this is a way of--if you can imagine, at a process food operation, each event has a certain likelihood of occurrence, and you can determine the overall occurrence, the probability of the top event occurring.

The Fault Tree has this sister called an Event Tree, and likewise, you can assign certain probabilities that certain events will or will not occur. In this case we have fire. Say, we have 100 fires a year. How many times does the sprinkler system work? Th probability is 95 times out of 100 they will, 5 times out of 100 they don't. So we end with 5 large out of control fires, which is a process failure, an unsafe condition, 95 controlled, which is successful, of course.

When you put the two together--and this is what is normally done--you have what is called a cause consequence model. So you start--here is the Fault Tree Model, like I showed two slides previously with these 5 event occurrence leading to the top event. T you can go further and analyze the probability of certain outcomes, using the Event Tr Analysis. And the main importance of this, I think, is, from our perspective in trying control safety of food, is institutional learning. It's very rare that anybody does a cause/consequence model, but it would certainly help in understanding what can go wron and what the likelihood of those events are. So I think it's something we need to be d more within this industry. Certainly if you factor in distribution and other factors t come to bear on safety of the food supply.

I said I'd mention human reliability, and the problem is, I came across the one, the reference cited, the 88/10/2 rule. I don't know why they couldn't have done the 80/20 like everybody else, but 2 percent of the time equipment fails. Categorically it's equipment failure. 10 percent of the time is some kind of other operational failure th may or may not be related to equipment. 88 percent of the time humans are responsible some of these failures. So when you're designing any safety program, whether it's HACC GMPs, SSOPs, whatever, certainly we heard to day about there's a number of workers on line culling the bad fruit. Well, don't rely on that for very much, because as I said, percent of the time they're going to fail the system.

But if you are going to put some effort into developing more reliable workers, these are some of the points that need to be covered. I'm running out of time so I won't go through all of them. There are 10 points that have been proposed. Here we have this te

MS. JACKSON: Dr. Slade, you have 2 more minutes.

DR. SLADE: Sure, thank you.

The estimate of the likelihood that errors will be undetected or corrected, so here again we have our risk consequence matrix. We have to estimate the consequences of tho errors.

So kind of getting close to the end here. Risk can be determined by analysis of the hazards and the severity occurrence and detection according to the FMEA model, the FME criticality analysis. Judgments are made. And this is how we then manage the risk, as indicated in that very first risk analysis chart.

The important thing here is how we build from HACCP to evaluate equipment failures using HAZOPS, through process failure, using FMEA, and then on to a full analysis, quantitative risk assessment using the cause/consequence model, ETA and FTA. So we go identification of hazards to a true quantification of hazards using a system such as t And that says that in a nutshell.

My work at the NCFST, I'm currently working on a program inactivating pathogens in

juice using high pressure. We are planning to model inactivation of pathogens using th system with different variables. What I'm going to propose to our members is that we continue this through to study--to develop a HAZOP study around this. It will probably the first in the food processing industry that I'm aware of, with FMEA as well. I'm reluctant to get involved in a Fault Tree Analysis development. There's a lot of work that. I think this will probably be enough to see us through the next year or two.

If you are interested in some background reading, there is some good documentation in 15-year-old document. It is a book by the American Institute of Chemical Engineers.

Very interestingly, there are a few people in the world that are also working along these terms. Serra and colleagues in Spain recently published a paper on risk assessme and critical control points from the production perspective. Serva Odomons in Holland fairly active in this field, and our own Don Schuffner over at Rutgers is thinking alo these lines.

So that is all I wanted to say. Hopefully, you can see where some of this may have som bearing on the issue at hand with respect to the juice industry, but also with respect safety in a lot of other food manufacturing industries.

Thank you.

MS. OLIVER: Thank you very much.

Our next speaker is Dr. Bruce Tompkin, vice president for Product Safety, Armour Swift-Eckrich, ConAgra Refrigerated Prepared Foods. He is going to speak on validation performance measures under a HACCP-based program for fresh ready-to-eat products.

DR. TOMPKIN: I have been asked to talk about validation. I approached this as though this was going to be a validation for juice in a generic sense, not specifically for oranges. So keep that in mind as we progress.

It is important that we all understand what we mean by validation, and this is our definition of validation. This is from our last advisory committee document, and it is really the important thing to remember is that we are collecting and evaluating scient and technical information to determine whether the HACCP plan, when properly implement will effectively control the hazards. Those are key words, and that is where we are go to be working from, but in order to do that, I would like all of you around this table imagine that you are a member of the HACCP team.

This building is our plant, our juice operation, whatever kind, and we produce juices that are refrigerated and sold to both retail and food service markets. We are the HAC team, and we must validate that our food safety control system will control the significant hazards. So we are all partners in this.

We recognize that our business is dependent that we have the primary responsibility to produce safe products, and our first priority is to produce a safe product. Our second priority is to meet regulatory requirements. Also, we recognize that we cannot be successful if consumers question the safety of our products.

We have one HACCP plan for our juice products. All our juices really just vary according to a variety of fruit, where we get them, the fruit, the blends that we may make, the packaging size.

We have already done a HACCP plan. We have done the hazard analysis. All we are doing at this stage is the validation.

A flow diagram might look something like this for our juice process, and it is going t go all the way from growing and harvesting all the way through to serving the juice, wherever that may be. In our particular HACCP plan, we may have one CCP, and we are go to validate that kill step, for example, or we may also approach it from another

perspective where we are going to have cumulative effects resulting from a series of s which may lead to a desired protection of the product and the consumer.

So the question is how can we validate that our juice process will yield a safe produc every time. We cannot afford to make a mistake.

Our hazard analysis led to two significant hazards, microbial hazards, salmonella and pathogenic E. coli strains. We used a process authority. We did not have enough knowle in our group. Excuse me. And we decided that listeria monocytogenes is not a significa hazard in our juices. So we have excluded that, and we are going to go with the top tw

We have learned that on rare occasions, however, that juice products have made people sick. What we have to answer to the best that we can, why did that happen, what went wrong.

The question is how, then, can we get this information. Well, our own experience, mayb we have had such a situation. Professional contacts. We may have worked for a company had a problem or we know people, our competitors, who have had problems, and we can ta with them. Certainly, the regulators can provide information and on down, including th process authority.

We collected all of our information and what can we summarize relative to the two significant hazards. Well, there are sources of fruit. They may be inside the fruit, a there is a question about that. They are not likely to multiply as we process the frui into juice, and no one to date has shown these pathogens to establish and multiply in environment for the processing juice, such as may occur with listeria monocytogenes in some cold refrigerated rooms. That has not been shown with this particular issue.

We have also learned that low numbers, as low as 10 cells or less of 0157 can cause illness, and these pathogens that we are concerned with are quite resistant to the aci the juice and will likely survive through the refrigerated distribution.

However, they cannot multiply below 45. So refrigeration is important, and they are actually readily killed by heat and chemicals and so on. So that is the basic informat that we have on the pathogens, but now where can we go to get information on some guid for control measures? We really now want to bring that information to bear. So, certai we can go to FDA regulations since juices fall under them, and State regulatory agenci departments of agriculture, extension agents, and universities are very helpful, and o down through that group.

The guidance materials that we have all assembled as a result of that process have led us to conclude that we need to do at least these things. First, as a group, we all agr that we should control the pathogens on or in the fruit before squeezing or pressing. can be accomplished by selecting the fruit, and how we go about doing that is to buy f selected certified growers. We can have purchase specifications based on grade and oth conditions. It may include varieties, if it was an orange juice.

We are going to exclude navel oranges, for example, as we heard this morning. That is not normal. The harvesting method is going to be important with no dropped fruits, the conditions of storing and transporting those fruits to our plant, and then we are goin have some sort of system where we are going to be auditing our suppliers, our growers, so on or whoever else may be providing the fruit to us.

We have go to remember, we do have a grove or two or an apple orchard. We have got to be just as stringent to ourselves as we are to our suppliers, something we tend to for sometimes in this business.

Certainly, this morning, all the materials that we have read--I have had the advantage perhaps, of having this apple cider thing that Art Miller gave me that was very helpfu It had some information in it, what we had this morning that has been passed to us bef we met, as well as what we have heard this morning, and from all of that information,

there is quite a bit showing that the benefits of, for example, sorting, washing, brushing, and D values have in fact been placed on some of those steps. So, certainly, know we want to apply that properly.

We also want to implement effective cleaning and sanitizing procedures for our equipment after shutdown, for example, or during operation where appropriate, and then certainly, controlling the temperature of the juice after we collected it.

So what reduction have we achieved through just those steps? Well, based on the information that has been collected and maybe a few tests that we have had done throug consulting laboratory, we feel that we have achieved at least a 3D kill. You could eas from that documentation or what you heard this morning comie up with a conclusion that have a 5D kill or a 6D kill. For this example, let's just start with the 3 and see whe that leads us.

The question now that we must answer amongst ourselves is: Will our control measures b adequate to ensure that our juice is safe? Do we need to include a kill step for the juice, and if so, do we really need as much as a 5D kill?

So the question, then, is: How much kill is needed to be certain that all lots are safe? As you might suspect, this depends on their number in the juice. So what is the actual number of enteric pathogens in freshly squeezed or pressed juice? Again, we hav go to the books, talk to people, getting outbreak information where outbreaks have occurred, what has been the recoverable level of salmonella or other pathogens. Perhap there have been some industry surveys, and we may actually have been doing some tests blended juices at the end of our process to get estimates on that.

This morning, for example, we did have some data presented earlier, and this was available to us in the handout that we received. I have reorganized it, and it shows t 17,000-plus for the 0157 and the 11,000. So this is a pretty substantial body of data four establishments producing juice over a fairly long period of time with essentially relying on the prerequisite programs. You could have a big debate whether CCPs are prerequisite programs, but that is not the discussion today.

They are all based on a 25-ml sample. So that is a substantial body of data that would indicate that the risk is quite low for the presence of these pathogens.

If we elect as a HACCP team to recommend to our management to include a 2D kill, then how are we going to go about doing this? Well, it could be done through UV with the ju of the right type where it can work or through high pressure, pulsed light, heat, and on.

I am going to take you down through an example as though we are going to apply a heat step. We are going to suggest that we are going to apply a 2D kill, and the question i what time and temperature do we really need. We can go to the literature. We can have tests done in the laboratory, and then, essentially, what we are looking for is this k of data.

For meat and poultry, I can fill in the missing blanks, but this is juice, and the information was not readily available in the time I had, but you are really looking fo what is the time for a 1D kill at these different temperatures, and then, from there, can get to the 2D kill by just multiplying.

At this stage, then do we have confidence in the safety of our product? I think based on everything we have done, our data, our scientific data that we can use as backup, w can say yes. We do have confidence in the safety of our product.

Have we met the performance standard that is the 5D kill? Yes, you could talk about th cumulative benefits of up to the 3D kill, and if we use the 5D approach, that gives us 5D. We are in compliance with the regulation, but have we validated the safety of our process? That is the question.

Yes, and I think we think so. We have confidence in it, but have we validated it from scientific perspective that in fact the juice is safe every time?

Have we controlled the hazards? We think so, but it depends again on the number of pathogens on the incoming fruit and then in the freshly squeezed or pressed juice, and the question is, will a 5D reduction ensure our products are safe. Of course, over her the left-hand column, it is number per gram, number per ml, number per square centimet That is a little fuzzy, quite frankly. We are going from per-square centimeter to per- but we will let that float.

So, essentially, it comes down to, if you go down to the bottom here, you can see it all really depends on how many are present in the incoming fruit. At a level of 1 per ml, I think we would all agree as a group here that that is not going to be a safe product, and maybe 1 per 1,000 might be okay, this question mark, 1 per 10,000 and on

How safe must we be to have confidence that our product is safe? How safe is safe, and how can we get to that question?

Well, I think it would be very helpful to have a clearly defined food safety objective and it is on that which performance criteria and so on are based. ICMSF has defined th FSO as a statement of the frequency or maximum concentration of a microbial hazard in food that is considered tolerable for consumer protection, and that is really where we going to. We want to have consumer protection, and so we need to know what value we ne as a target so we can design our process to deliver that consumer protection.

As an example, I did not fill this in exactly, as you can see. I chickened out, but we are going to do that tomorrow, maybe. The number of enteric pathogens, for example, th things, will not exceed, or if you want to word it differently, shall be less than X/Y at the time the juice is consumed.

So the FSO, as you can see, defines the goal by which we in industry must drive when w design our process. In addition, it gives the basis for agencies to assess whether the total food safety system will deliver the expected level of consumer protection, and t as you could see, a performance standard, the 5D kill or log reduction, I should say, not really ensure safety unless the pathogen concentration is known or conservatively estimated at critical steps in the process.

We are missing something.

So what is necessary for consumer protection? While I was on vacation during the last stint of the advisory committee for 2 years, you folks decided in 1996 that a tolerabl level of risk could be achieved by a validated process that provides a cumulative 5-lo reduction and so on, or it was interesting also, a reduction in the risk of illness to less than 10^{-5}, assuming 100 ml of juice is consumed daily for a year. Well, 365 days times 100 ml with no problems, that means you are going to be consuming that quantity, but what does that really mean? I could not quite figure that out, but that okay. We will go to another one.

There was a memo written to the record for FDA to document the deliberations of the committee as they discuss this issue, and this also contributes to it. So they work fr the basis--this is one approach--that some samples of cider may have 1 E. coli--this i normal E. coli per ml--and if they were pathogenic, then a reduction to less than 1 pe serving, assuming 100 ml, would be necessary. Then you would have less than 1 per 100 However, if the standard is 100-fold safety margin, then you are going to have to bump that to 10^{-4} per ml, or at 5-log reduction. You can see that the 10^{-4} per ml is 1 cell per 10 liters or essentially about 2-1/2 gallons.

The ICMSF has proposed the following guidance material, and this information incorporates the FSO. This is a formulation that the ICMSF came up with. There was a s reduction as the total, reduction of the hazard throughout the process. Also, the sigm

is for growth or increase. It also includes contamination that may occur from the haza throughout the process.

The FSO, of course, the initial level of hazard is included in here as H_o. R, by definition, is negative, and growth, of course, is positive. Here is an example, then. If we have an FSO for an infectious agent of equal to actually or less than 1 CF per 100 grams at the time of consumption and we have an FSO of 10^{-2}, we have an initial level in this example of 1,000 per gram or $\log_3$. There is no growth in this example. So you can see through the equation that we get down from the sigma R pl zero is equal to or less than the minus 2 and the minus 3, and that leads to a sigma reduction being required of equal to or minus 5. So the process in this example must result in an overall reduction of at least 5 $\log_{10}$ units, from 1,000 down to .01 per gram, and that is a performance criterion that could be derived from that of a log reduction.

Graphically, it would look like this up on the top. You have a dose response for this infectious agent, whatever it may be. So that, as the dose increases, the level of ris certainly would increase to the consumer, the orange portion.

In this particular example, we feel that equal to or greater than 1 per 10 grams is unacceptable, and that puts it short of the unacceptable level of risk, but we want to build in a little cushion in terms of consumer protection. So we say our FSO is going be 10^{-2}.

Down in the lower box, we have the FSO of 1 per 100 grams, the initial level in this case being 1,000 per gram, no growth, and again the equation. You can see we are going go from the right of 1,000 per gram to achieve our FSO of no greater than 1 per 100 gr Essentially, that takes into account, then, the starting number where we are trying to It builds in, then, the performance criteria or log reduction. So it gives a complete package. It allows us to know where we are going.

Thank you.

MS. OLIVER: Thanks very much.

With that, we will go into our next session of questions for clarification for both Dr Slade and Dr. Tompkin. So I would ask the committee if anyone has any questions.

Bill?

DR. SPERBER: Yes. I just have one point of clarification on Dr. Slade's talk, and this might bore most of you, but I think it is important because HACCP is such an important concept.

Peter, you showed a military standard from 1969 that looked a lot like HACCP, and you said this actually predated the development of HACCP by Pillsbury and NASA, but, actua the military was part of the team with Pillsbury and NASA and that started in the earl '60s. In fact, through the U.S. Army labs at Naddick, the military brought in the idea FMEA, and that in fact was the seeds for HACCP.

The date 1971 comes into play because that is when Pillsbury first published the HACCP approach describing how it had been working on these Government contracts, and in 1972 Pillsbury began applying HACCP to its own consumer foods-producing plants.

Of course, now the rest is history. HACCP is widely used and abused around the world, but I think it is important to keep the history right.

One of my favorite philosophers, A. Whitney Brown, says there is a great difference between the past and history. The past actually happened, and the history is just what somebody wrote about.

[Laughter.]

DR. SLADE: Thanks for that, Bill. Maybe you could help rewrite the history or write th history.

I think the important point is--and I was not aware of that background. I was around, but I was not around doing this then.

I think FMEA from the point of view of looking at the probability, the likelihood, and the severity and then perhaps developing some kind of equation may be useful because w can put numbers to some of these process-type failures. Thanks for that. Maybe we shou write a paper on the history of HACCP development, including those things. That would very useful. Thanks.

MS. OLIVER: Thank you.

Bob?

MR. BUCHANAN: Thank you, Janice.

Now I know why we keep these old guys around.

[Laughter.]

MS. OLIVER: Bob, please identify yourself for the record.

MR. BUCHANAN: Bob Buchanan, FDA.

I have a request, other than a question. We have been receiving a great deal of material today, and it is not all in our notebooks. Could we please request copies of presentations? Most have been in the form of slides or PowerPoint presentations. Could ask that all of those be printed out and distributed to members of the committee?

MS. OLIVER: Yes. We have got copies of some of the presentations. We do not have copie of all. If you would, give to Kathy DeRover who is in the back, at the table back ther She will ensure that they are printed for the committee.

John?

MR. KOBAYASKI: John Kobayaski, Washington State Health Department.

During the investigation of the latest orange juice outbreak, we had a copy of the label or the cap from one of the orange juice containers which said HACCP-safe. I gues question is: What went wrong, or what is your opinion of what went wrong?

Now, I realize an easy answer is, well, HACCP did not fail. The adherence to HACCP or whatever failed, but it would seem to me that maybe in simplistic terms, it was sort o ignoring the effects of Murphy's law that things go wrong. It seems to me that part of HACCP is to assume that things are going to go wrong and that there needs to be some s of safety net involved. Do you have any comments?

MR. TOMPKIN: You are asking me what went wrong?

Actually, I think it is critical for us as a committee to know in each of these events It is very difficult to design safety into a process if you cannot learn from past experience. Otherwise, it could happen again.

We need to know what went wrong, what did occur, so that we can prevent that. I do not know the answer. I have heard an answer, but I think somebody else would be better sui to address that.

DR. SLADE: I do not have the answer either, but i just want to comment. I mentioned that Don Zync, who is from Nestle, has told us that we do not need more risk assessmen in the work we do. I kind of disagree. I think some of these techniques lend themselve very well or are very suitable for the job at hand, but Don has made the point that HA does not fail. It is just execution of the HACCP that generally leads to a system fail That is one of the points I was trying to make, but it leaves HACCP with a black eye.

Regarding the documentation and the archiving of these types of failures, there was a lot that should have been learned from the Schwann's Ice Cream outbreak, which may hav been useful with respect to the orange juice episode with Sun Orchard.

Application of FDA cause consequence analysis, which would have been institutionalized perhaps would have been useful in learning those lessons of history, and that did not happen.

MS. OLIVER: Mike?

DR. DOYLE: This is Mike Doyle, the University of Georgia.

Peter, I was intrigued by your concept of risk priority number. Have you calculated what the risk priority would be for fresh orange juice, and if you have, how does that relate to other foods?

DR. SLADE: I am not a mathematician. I can hardly spell "bouillon," bouillon algebra. I am hoping somebody will take that on. I have suggested I am going to propos that to our members when we look at our working groups back at the national center and develop that as a project and find out how we can do that, but I have not done it.

Bear in mind those caveats as well. These just help us identify where we should put ou priorities. It is not a be-all and end-all number kind of thing, but it is just so we allocate our resources and prioritize those allocations.

MS. OLIVER: Dan?

MR. ENGELJOHN: Dan Engeljohn with USDA.

This is directed at Bruce. On the food safety objective that you identified, how do yo factor in the population, whether it be a vulnerable population or a normal healthy population? Then, how do you establish your initial population in terms of the microbi level of the pathogen?

MR. TOMPKIN: It had to do with the number of cells per ml of juice, for example. All I did was to go through the information, and it would appear in the case of the apple ci anyway, it indicated there was 1 E. coli per ml occurred on occasion. It would appear there was a survey, as John Freund mentioned, on fresh squeezed juice on a variety of situations throughout Florida, and they had 2- or 3-percent positives. I think that mi even be in the information, too, but it was a relatively small percentage of positives and then it was a question of what is the number there.

The best way to do it actually is to pull samples in the process and determine what is the number of coliforms, E. colis. Essentially, one thing that you might keep in mind your goal should be an E. coli-negative product in this particular case, keeping in mi that is a conservative approach to enhancing safety. If you can deliver an E. coli-negative product, then the risk that salmonella or 0157 may be present would be lower, also. Essentially, that is what we do with fermented products, dry sausage. We not want to have an E. coli-positive product.

With regard to how do you build all this in with the food safety objective for the general public and for higher-risk individuals, that really comes down to how conserva do we need to be, recognizing that in the case of juice, you are going to have childre

consumers.

If it is an 0157 situation, they are going to be at greater risk. So, essentially, we have got to build as a group here. We are going to have to decide if we take that path are going to have to decide what should that FSO be, what should the value be in order ensure that there is a very low likelihood of an illness from the class of product. So it 1 per 1,000, 1 per 10,000 ml? Where are we going to go with that?

MS. OLIVER: Dane.

DR. BERNARD: Thanks. Dane Bernard.

I have a question for Peter, but let me just continue with the discussion.

Dan asked a question of Bruce on initial pathogen load. I think it is one that we have to put a good deal of thought into. In Bruce's vacation from the committee, when the 5 recommendation was discussed, there was very little information available. There is st relatively little information available, but there is more today than there was at tha point in time.

We have had some opportunities to gather data on product that has been involved in outbreaks, and I think as we go forward, it would be good to have that information to consider.

Obviously, when we are talking meat and poultry products, and Bruce mentioned sausages we are talking about a raw material that one expects to have a certain background leve human pathogens associated with. Enterics are associated with warm-blooded animals. An orange is not a warm-blooded animal. So we do not usually expect it to be there. So we talking about an unusual event.

So I think when we talk about initial pathogen level, we have got to look at the unusual events and try to figure what might have happened to cause that and what the levels might be so that we can assess what the target food safety objective might happ to be.

Back to Peter's presentation, Peter, you were talking about human reliability at one point in your presentation, and one of the points that was made this morning was the effectiveness of sorting products. Correct me if I am wrong, which I probably am. You mentioned human reliability as factor and about an 88-percent failure rate, I think. I would like to get some clarification on that because I do not think you meant humans f 88 percent of the time, but 88 percent of the time when there are failures they are associated to human factors.

DR. SLADE: When there are failures, yes, they are associated 88 percent of the time to humans. That is at least in the one study that I have seen.

DR. BERNARD: I know personally, probably in the 88 percent do not make a category, but that is not what you said.

DR. SLADE: That is not exactly what I said, no.

Just on that point, there are a lot of aspects to these workers. Presumably, there is high turnover of those workers. It is very hard to get the culture instilled in them. is hard to train and educate those types of people very effectively, and that probably explains why motivation and other things leave a lot to be desired.

MS. OLIVER: Does anyone else on the committee have any comments or questions for clarification? Does anyone else have any comments or questions for Dr. Slade or Dr. Tompkin?

[No response.]

MS. OLIVER: With that, what I think I will do is take a 15-minute break, and then we will open it up to public comments and we will get ready for that section.

Thank you.

[Recess.[

MS. OLIVER: The first group of speakers have 5 minutes apiece. They are individuals wh have registered before September 1st. We have a number of speakers who have also registered today who will have 2 minutes apiece. We will be keeping time, also, to let know, and the first speaker is Charles Royal from Congressman Weldon's office.

MR. ROYAL: Good afternoon. My name is Charles Royal. I am on the staff of Representative Dave Weldon. Unfortunately, the Congressman could not be here today bec of other duties, but he thought it was critical that his concerns be raised before thi panel. He asked that I come here today and read his statement on his behalf.

Members of the committee, I am an internist by profession. For 15 years, before my election to Congress, I worked as a physician. Since my election to Congress, I have continued to volunteer my medical services on a monthly basis.

As a physician, I have a strong concern about protecting the safety and quality of foods and beverages consumed by the American public. I also share this commitment as a Member of Congress, whose duty it is to serve the public, the entire public, both the consumers and the producers.

It is for these reasons that I take an interest in the issues before you today. I read with concern the stories of outbreaks of E. coli in apple juice in the northwestern Un States several years ago. Indeed, I have treated many patients suffering from foodborn illnesses in my medical practice. The FDA appears to have taken appropriate action wit respect to ensuring the safety of apple juice for the consuming public.

When I first heard that the FDA was considering applying the same standard to orange juice, I was very concerned. Representing a citrus-producing district, I have enough knowledge of the citrus industry to know that the juice-making processes are very different. I visited Orchid Island Juice Company in my part of Florida because I know their good reputation for providing a good-quality product and their commitment to saf processes.

I was pleased to help set up a meeting between the FDA and Orchid Island to address their concerns about the agency's plan to treat oranges and apples the same. I am incl to vigorously oppose any effort to treat apples and oranges the same. I am pleased tha the FDA has undertaken a Hazardous Analysis Critical Control Points, HACCP, demonstrat program with Orchid Island. From all that I have seen of that program, it has proven v successful. They have strong quality controls in place to ensure a safe product. They USDA and Florida Department of Citrus inspectors on site whenever juice is being processed, not as a result of the program, but as a result of the Florida HACCP progra They are a business that knows how important safety and quality is in protecting not o the health of their customers, but the business that they have worked so hard to build One outbreak of a human pathogen could destroy their entire business. Clearly, they wo not jeopardize everything they have worked so hard to build. I urge the committee and FDA to recognize this fact.

In addition to having inspectors on site around the clock, Florida's regulations require the testing of each batch of orange juice for pathogens. In all of the tests conducted on their juice since the Florida HACCP regulations were implemented, harmful pathogens have not been found in Orchid Island juice. Clearly, something right is bein done here. I ask the committee and the FDA to recognize this fact. There is a way to ensure a pure, fresh product.

Further, I would ask the following questions be considered. Has there been an outbreak of salmonella or E. coli in fresh squeezed orange juice that has been produced under Florida's HACCP program which was put in place in 1996? The answer is no.

Has there bene a positive reading for salmonella or E. coli in the more than 17,000 tests of fresh squeezed orange juice from four producers that were a part of the recen study? The answer is no.

While no one will deny that there have been fewer than a handful of outbreaks of pathogens in fresh juice not regulated under a HACCP program, it would be an oversight forget to take note of the fact that there have been numerous recalls of pasteurized o concentrate product for contamination. That is right. There have been failures in syst for pasteurized juice products.

This points to the fact that there must be clean processes to protect both pasteurized and non-pasteurized products from contaminants. Just because something is pasteurized not mean that there is 100-percent surety that it is free from pathogens or contaminan A quick scan by my office easily found more than 12 to 14 recalls. One even stated tha individuals had developed foodborne illness.

An unclean process, whether in fresh or pasteurized products, can result in a product that is not free of pathogens. Clearly, the solution is not to require that all juice products be pasteurized.

Also, the infiltration studies recently issued by the FDA have been subject to very little scrutiny. However, what little scrutiny has been done should raise serious questions.

First, the dye update study. This study has no relevance to the fresh juice produced b companies like Orchid Island. They do not immerse their fruit as a part of the washing process.

Second, the infiltration studies. These studies showed a small uptake of pathogen through the stem scar. That is logical. However, how often in the normal processing of fruit is there going to be an application of a 7-log pathogen on each stem scar? Furthermore, the FDA has done nothing to show that even if there is an uptake of a sma amount of pathogen in a small number of oranges through a stem scar, that this would happen during processing or that it would cause a health concern. In fact, all of the evidence thus far demonstrates that infiltration does not exist in current practices, does it pose a threat to the public. If infiltration was happening on a regular basis, wouldn't you think that at least one of the 17,000 tests conducted to date in the stud presented by Dr. Strobos would have tested positive for pathogens? Wouldn't you expect that the Florida Department of Citrus or the USDA to have found a positive reading of pathogens in their mandatory tests of each bath of Orchid Island juice? Is it appropri to consider the preemption of a Florida State law that is working?

With regard to the questions before the committee today relating to internalization of pathogens, while internalization of pathogens may be theoretically possible under extr conditions in an FDA lab, the evidence does not support this being the case in the fie It is a fallacy to assume that because you can produce a result in an FDA lab, that th process replicates itself in nature or in juice processing.

Indeed, I would argue that if the infiltration studies are accepted as replicating wha occurs in nature and processing, the adverse impact would extend far beyond the citrus industry. Far from simply affecting the regulation of fresh juice, if the committee an the FDA accept infiltration of pathogens as a naturally occurring threat to the Americ public, as question number three would imply, the entire fresh fruit and vegetable industry of the United States will be threatened, and public confidence in consuming f fruits and vegetables would be undermined. Sending the American people the message tha that consumption of fresh fruits and vegetables is unsafe would be a dangerous and fal message.

I would urge the committee in the strongest terms to reject this assumption. It is based on flawed research and does not pose a public health concern.

Unfortunately, at the present time, it appears to me that the proposed FDA regulation is seeking to apply a solution to a problem that does not exist. If we have a problem a company importing Mexican juice and adding tainted ice to it, let's correct that problem. If we have a problem with frogs swimming in juice, let's address that problem the State of Florida already has. If we have a problem with unclean processes being us in the production of unregulated fresh juice, let's address that problem, but let's do apply an unreasonable, unachievable regulation or an over-reactive label to a safe product.

I thank the committee for allowing me this opportunity to share my concerns with you.

MS. OLIVER: Thank you.

The next speaker is Alan Reynolds.

MR. REYNOLDS: Thank you.

My name is Alan Reynolds. I am a citrus grower in Fresno, California. I thank you for the opportunity to address your committee on this subject of extreme importance to the citrus industry in California. I am here today to speak to your concerns regarding microbial contamination in fresh oranges, specifically highlighting proactive measures California fresh orange producers are doing to prevent and/or reduce the risk of micro contamination.

First and foremost, California citrus producers support research through a grower-funded citrus research board, allocating those funds to projects, focussing on, among other things, fruit quality in pre- and post-harvest operations.

In establishing this research board, growers recognize the need to have a quality assurance program in place specifically to address issues such as this and continue to fund such a fresh citrus quality assurance program.

The specific example of the type of projects funded through this program is one funded this year specifically to look at improving sanitation systems in the packing houses w emphasis on spore suppression in all areas of the packing environment. The work is to carried out by a University of California post-harvest researcher, Joe Eckert, and it directly relates to eliminating microbial contamination; in this case, plant pathogens

As a result of some concern regarding microbial contamination, representatives from th FDA came to California in 1998 to review practices in the California citrus packing an handling industry. Those representatives took away a favorable impression of Californi packing industry expressing confidence in the industry's current practices, which as I mentioned before we continue to strive to improve.

In addition to post-harvest activities, California producers can be proud of the strides made in orchard practices, which help in eliminating potential contamination sources.

First, California producers follow stringent laws and regulations surrounding field worker hygiene and sanitation practices. These regulations include the availability an maintenance of sanitation units, clean water and soap for hand-washing, among others. do repeated training sessions to remind workers of those requirements and why they are place.

In addition, most California citrus is under some kind of pressurized irrigation syste utilizing drip or low-flow irrigation technology, which applies the water under the tr substantially reducing the possibility of contamination through the irrigation water.

To facilitate this irrigation, trees are skirted to keep the lower branches off the ground. This practice also keeps fruit from contact with the ground, reducing fruit contamination.

The ground in orange orchards in California is kept clean of weed, a clean cultivated ground, which further reduces the possibility of contamination. In addition, by keepin clean cultivated with no weeds or ground cover, animals do not enter citrus groves to graze, and as such do not put further threat of contamination.

Disease and pest control decisions made by California producers are made with fruit quality concerns in mind. This includes rodent control which is vigorously pursued to substantially reduce or eliminate rodent population in groves. Good fruit quality is essential as a first step in putting out a high-quality packed carton and reduces the possibility of contamination by plant pathogens and, by definition, other pathogens as well.

Once again, thank you for this opportunity to address your committee. California fresh orange growers are committed to providing a quality wholesome safe product and make ev effort to be certain that our California fresh oranges remain so.

Thank you.

MS. OLIVER: Thank you.

Donald Roark?

MR. ROARK: My name is Donald Roark. I have been growing oranges in central California for the past 35 years. For the past 30 years, I have been also involved in packing hou management, particularly in the field harvesting coordination for this firm.

Over the last 30 years, I estimate we have harvested over 5 billion pounds of oranges in our own organization. During this time, we see no reports of any fresh illnesses fr our fruit, either in the fresh whole orange form that we sell the fruit in or in the f squeezed point-of-purchase fruit that our fresh whole fruit is used for.

Today, I want to offer comments in a couple of areas of our production that may be helpful in the understanding of the steps we use to assure a quality, sound orange rea the end of our packing line when we are involved in the production of fruit.

These areas are the outside inspection agency that assists us in grade and quality standards and the fruit harvest operation itself which is vital to maintaining a sound product throughout the whole system.

First of all, the State of California has grade and maturity and quality standards for California citrus. These laws are enforced by the California Department of Food and Agriculture. The local enforcement is done by county enforcement commissioners. The St of California supervises the county commissioners to make sure there is uniformity in enforcement and does quality control checks at the end of the food chain as well.

Several years ago, the county commissioners in certain counties were having a hard tim making budgets to fund this kind of quality control, work that is most beneficial to o growers and packers, as well as to consumers. Our industry passed legislation which mandated a check-off system for all growers, and now we supplement county and State fu with grower funds to make sure these standards are enforced effectively and uniformly throughout the entire State.

The items that are important in the quality standards that the State enforces are maturity, color, and frost, and as well as other grade and standardization units invol the fruit.

On-site inspection is done by county inspectors. In the case of maturity, the on-site is actually out in the orange groves themselves, and these people are entirely an outs agency, even though we supplement the funding through the local county boards of supervisors.

The other area I would like to address briefly is the harvesting aspect of citrus. We feel in our industry that if you have fruit quality problems, particularly with decay mechanical injuries, the bulk of these are going to occur in the field. There is a num of things that we do in harvesting that is important to prevent this.

One of the foremost is the training of workers, the human aspect. We have a year-round production of citrus in California. We have a fairly stable work force. We have been a to develop training programs not only in orientation, but further training in hygiene, health, safety, and pesticides, and we have discipline procedures to back these system up. They work.

Some of the areas that we particularly train on and work with in fruit harvesting are the use of the fruit clipper. The fruit clipper is a mechanical clipper held in the ha of an orange harvester, and all of our fruit that is destined for packing houses--

MS. JACKSON: You have one minute remaining.

MR. ROARK: Thank you.

--is used with a clipper. We also will not allow fruit to be harvested from the ground This is vital. If there is a substantial amount of fruit in the grove that has splits rots, we will go through the grove several days prior to harvest and drop that fruit o the ground.

As has been said earlier, there are sanitation facilities on site. They are regularly maintained and inspected according to State standards.

Further is good management practices in harvesting fruit. If there is an external even such as a hail storm, wind storm, sand storm, or frost, we do not harvest for many day afterwards until the effect of that can be evaluated and the damage from those sort of events can be seen on the fruit where we can cull that fruit out readily.

As well, we avoid harvesting in wet conditions where mechanical injuries are more prevalent and will damage the fruit easier.

Thank you very much for your time.

MS. OLIVER: Thank you.

The next speaker is Jimmy Benincasa.

MR. BENINCASA: My name is Jimmy Benincasa. I am from a company called Hale Indian Rive Grove in Vera Beach, Florida. That is Indian River County, Florida.

I am the juice division manager there, and we have a small juice plant. We do not process juice on the scale of some of the other companies that you heard present information to you today. However, I handed out to you a laboratory report. It is enti Siliker Laboratories, Incorporated. It is a research report that validates actually 7.25-log reduction in one step. I would like for you to take a look at that as part of your decision.

Hale Indian River Grove has been in the juice business for more than 50 years. It is a privately owned company. The owners are still active in the company. I am not an owner am just an employee there.

However, we process about 300,000 gallons of fresh citrus juice on an annual basis,

which equates to about 4- or 5-million 8-ounce servings, and during the 52 years that Grove has been making orange juice, there has never been reported to us or we are not aware of anyone who has ever gotten sick or had an illness related to drinking our jui

When the FDA requested that we validate a 5-log reduction as part of our process on th

surface of the fruit, we decided to add an additional step. We washed and sanitized, l some of the other companies that have been here already today. We washed and sanitized fruit. We wash it with an SOPP, which is a high-pH soap. We rinse it. We visually insp it. We chlorinate it with 200 parts per million for 45 seconds. We re-rinse it with potable water, and then we decided to add an additional step. That additional step was steam tunnel.

So we constructed a steam tunnel where we submit our fruit to 175-degree temperature i this tunnel for 72 seconds. Now, why we chose those numbers--I come from an industry w I used to pasteurize, in the egg industry. I do not know why I set on those numbers, b we can change those numbers. I can make it 180 degrees. I can make it 60 seconds. I ca make it 120 seconds, but that is working for us. If you look at that study, that study shows that that steam tunnel alone is getting a 7.25-log reduction on the surrogate th we were given by the Department of Citrus to use.

Now, we did this in our plant, this study. We introduced the surrogate in our plant. W did three trial runs, and that has now become our critical control point. The chlorina and sanitizing steps for us are now just backup steps. We believe we are getting a 10- reduction on the surface of that fruit because if you study the reports done by the Department of Citrus and others in the field, washing and sanitizing the fruit, as we gives us a 3-log reduction, at least a 3-log reduction. Now sending it through this tunnel, we are getting another 7-log reduction. This report only tested the steam tunn It did not test the rest of the process.

After it leaves the steam tunnel--

MS. JACKSON: You have one minute remaining.

MR. BENINCASA: Thank you.

After it leaves the steam tunnel, it is reinspected, visually reinspected before it is extracted.

I wish that you as an agency can give us regulations that would incorporate some of th things that we are doing at Hale Indian Grove and some of the other things that you ha heard.

The problem here is that people are getting sick not because of salmonella in the fruit, but they are getting sick because of an absence of good processing regulations. have some of those in Florida, and I think they can even be implemented further, and w need it enforced.

That steam tunnel process is being duplicated by other processors in Florida. I have had other small processors come to our plant. They are copying that equipment. They ha already installed it. I know of one plant that has already installed it, and it is up

working.

Somebody asked earlier why would we object to pasteurization. I would just like to answer that briefly. I would object to pasteurization because--

MS. JACKSON: Your time is up, sir.

MR. BENINCASA: I thank you.

MS. OLIVER: Finish your sentence. You can finish your sentences and wind up when your time is up.

MR. BENINCASA: People come into our store to take juice back to Minneapolis or Michiga or Ohio, and, you know, they do not have to do that if we pasteurize it. They can go t the store in Michigan and get it from Tropicana or Coca-Cola, and if you want us to pasteurize our juice, by the standard definition, Coca-Cola and Pepsi Cola are now our competitors, and little companies like ours are gone. We cannot compete with those peo nor can the people who want that juice find that juice anymore.

Thank you.

MS. OLIVER: Brad Barnhorn?

MR. BARNHORN: That was probably a good segue because I am from the Midwest, and I represent the Fantasia Fresh Juice Company, which was a company born in 1998 out of Chicago. So we have heard a lot today from California and Florida. I come from the Heartland and have some views on this, also.

We are a very unique company. We were born after the Odwalla outbreak. About 14 months after that was when we produced our first bottle of juice.

Of our ingredients, 41 of 42 ingredients are pasteurized. We use one pasteurized ingredient which is fresh squeezed orange juice. To make that, we do some things very differently. We only use pack house fruit out of Florida, U.S. Grade No. 1 fruit. We p about 50-percent more than any other juice company pays for their fruit, but that is w we pay for that safety to be in the product. It is the same product that would go to a Dominics or a Jewels store in the Chicago grocery stores or a Safeway or whoever else. we pay a premium for that.

Within our facility, we have a HACCP program. We do full scrubbing and rinsing. We hav had the 5-log validated by an outside firm, and we have gone through all of these processes.

So, as I have listened to all of this going on, I would just appeal to the common-sens side, but also the science side. I am not a scientist. I do like thinking about logic, I have heard a lot of very interesting arguments here, but when I hear some things, fo example, about Murphy's law, I understand Murphy's law, but if we are going to make regulation based on Murphy's law in an example of an orange truck running into a truck full of dung, I as a common-sense individual would not use oranges that had gone throu that process in my production. I think there is a limit to what can be said in that regard, and at that point, fact and not conjecture is what is relevant.

One thing that I have sort of had a real challenge with as I have watched this whole process unfold is I have not seen where the pasteurized orange juice industry has been part of this process to speak about the same challenges that maybe they have in other areas, the same level of scrutiny being applied to our industry.

I would like to have seen some people from the major pasteurized juice companies stand here as well and answer such a flawless safety prerequisite and flawless record of performance that we are being put on ourselves. I have not seen that. I have heard no comment from that area. They have been silent bystanders, and why not? Ninety percent the juice consumed in this country is pasteurized orange juice. Two percent is fresh. we are a small group, but that does not mean that equal attention should not be given what has been proposed as a solution to the problem.

I would like to see before us solutions offered, that solution being tested the same level of veracity which this group has approached, the apparent problem, despite the f that that indicates the problem is not at the level being proposed at certain points.

So what I want to say here is really to present that side and just ask that if you are

going to err, please err on the side of fact and not theory in this process.

Thanks.

MS. OLIVER: Thank you.

Steve Bogen?

MR. BOGEN: My name is Steve Bogen. I am with the Fresh Juice Company. I have been in this business for about 15 years. When I started, I was one of the youngest in the industry.

I got into this business because I believed in fresh squeezed orange juice, and I stil do. It is a product that is delicious. It is healthy. It is nutritious.

Forgive me. When Laurie Girand talks about what has happened, I have a 4-year-old daughter. We all have children, and everybody in this room feels for them, but when we confuse the processor and the process, when we compare apples to oranges, this is wron When we try to--I apologize. I am not really prepared for this.

Any product can be manufactured badly. Any product without HACCP can be made unsafe, even when it is pasteurized. All I ask is that this organization, that this panel, tak the time to review the facts and that is it.

MS. OLIVER: Thank you.

Peter Chaires?

MR. CHAIRES: I am thankful to be here today to provide comments on behalf of the American Fresh Juice Council, a national association of unpasteurized juice producers committed to ensuring a safe supply of safe unpasteurized juice for American consumers and the Florida Gift Fruit Shippers Association, a citrus trade association and shippi cooperative comprised of small roadside citrus businesses specializing in unpasteurize fresh citrus juice.

To preface my remarks, this meeting is a time to determine conclusively if the assertions about internalization have merit in a practical sense and I appeal to the committee to hear the words of reason spoken from Drs. Ismail, Pao, Parish, and Strobo this is not about whether an orange can be forced to internalize microorganisms under extreme conditions, but rather about what really occurs in nature and within common industry practices.

The ripple effects of this meeting stand to be significant for both fresh juice and fresh fruit, and the AFJC implores this committee to base their decisions on solid reasoned science and a keen understanding of real-world conditions as you have heard t described today.

My first point, risk and reason. The AFJC knows of no illness associated with the consumption of fresh citrus fruit, as was spoken to earlier by Dr. Ismail. Again, this seemingly an effort to move the focus away from the producer and the producer's responsibility and production practices and condemn the entire category.

Since 1996, quality operations have expressed billions of oranges, runs tens of thousands of micro tests without a positive detection for pathogens. If specific pract are thought to be responsible for contamination, address those practices. If a contamination under identical circumstances would have just as surely contaminated any other food product, it is inappropriate to contribute the cause of the contamination t fresh citrus juice.

Secondly, the equity of the proceedings. Base assumptions within the research are not

consistent with growing conditions, fresh fruit packinghouse practices, or fresh juice facilities. The scales of justice, in our opinion, are tilted. The agency must merely prove a positive, that under circumstance, no matter how improbable, internalization c occur in the raw fruit. The industry, with our limited resources, must then prove the negative, that internalization cannot occur under any circumstance, certainly not an enviable position to be placed in. Reason must play into the equation. The American Fr Juice Council is hopeful that the Committee will listen to the reasoned basis on which industry objects to the internalization argument.

Thirdly, misperceptions about alternate technologies. Although alternatives are in the works, pasteurization in its traditional sense is the only available alternative today Pasteurization is not simply an additional process step. You cannot have pasteurized f juice. Pasteurized citrus juice is a distinctively different product, and it is viewed such by consumers. Our customers want an unprocessed juice. They want a live juice wit superior taste profile and healthful properties. Our customers are not enamored by the concept of a minimally processed product.

Fourthly, misconceptions about pasteurization. First, the impact of mandating it because the very attributes that attract people to fresh product would be destroyed. A was mentioned, many small businesses would in a sense be regulated out of existence. A discussed in 1996, this is not a cure-all. The AFJC would far rather see the focus pla on front-loaded sanitation, good manufacturing practices, and HACCP plans than a rear-loaded safety net kill step. It makes little sense to force small firms to pasteu when we heard at an FDA meeting last July here in Washington that little is known abou some of the small-volume pasteurization units on the market regarding reliability, standards, and effectiveness.

Finally, what to do. We recommend that this Committee should recommend that FDA--

MS. JACKSON: You have one minute remaining.

MR. CHAIRES: --take the Florida model and expand it nationally by concentrating on strict adherence good manufacturing practices, firstly; secondly, a quality 5-log HACC plan, and HACCP plans should be required of all producers of citrus juices. This inclu pasteurized and fresh, large and small. There is no logical reason why the size of a facility should have any bearing on the applicability of safety standards. And inspect FDA should support and initiate a coordinated nationwide inspection effort. This progr could be a cooperative effort between USDA, FDA, and state departments of agriculture. This has worked in Florida. It certainly can work elsewhere and should work elsewhere.

And, finally, pursue producers operating outside known safety parameters and discontinue broad assertions about the category industry problems when there certainly isn't any compelling evidence that there is an industry or a raw product problem.

Thank you.

[Applause.]

MS. OLIVER: Thank you.

Next is Dan King.

DR. KING: My name is Dan King. I am the corporate quality assurance director for the Saratoga Beverage Group. I stood before you this morning hopefully helping to explain of the details of what we have presented as information from our consortium, a group o four plants. What I'd like to do this afternoon is speak more just from the Fresh Juic Company, which is the primary company owned by Saratoga.

Fresh citrus juices processed under the requirements of food safety-based GMPs, a validated HACCP plan that includes a 5-log reduction, and verified by pathogen testing programs, clearly can allow us to produce juice safely. With operations being carried

under the inspection systems, such as we have with the USDA Agricultural Marketing Sys the adherence to procedure for the safe production of fresh citrus juices is independe assured and documented.

This morning we presented a fair amount of data we believe established we have an enviable record among the four companies of producing a very safe product. We were par data being generated trying to determine whether issues such as internalization or failures in 5-log have been established. We don't believe the data does establish internalization, and we've seen no data that establishes failure in the 5-log process through the juice extraction step.

The Fresh Juice Company considers itself a leader among those trying to find out exactly what goes on during the process. We go a further step beyond what we firmly believe is a safe process, including the HACCP 5-log and 5-log reduction plan.

We test our fruit coming off the truck. We test it through multiple steps throughout the process, seeking to help establish just how much pathogen is there in the incoming fruit, how much pathogen, if it's there, can survive through the process.

This program is relatively recent. I do not have enough data to make a firm statement other than to say to this point zero, no pathogens nowhere.

In addition, we take further steps to guarantee what we think is also the primary issu that all of us are looking for: How do we prevent contaminated product from reaching t consumer? At the Fresh Juice Company, we take the additional steps of testing our prod at the tank level for the presence of pathogens. From the time we move it from the tan into our finished product packaging, we test it again for the presence of pathogens. A we do not allow that product to leave our facility until we have the results of that pathogen testing. We utilized a positive release program.

Our purpose is the same as yours: to produce a safe product and to prevent non-safe products from reaching the consumer.

Thank you.

[Applause.]

MS. OLIVER: Thank you.

Allen Matthys?

MR. MATTHYS: Good afternoon. I'm Allen Matthys, vice president of regulatory affairs, representing the National Food Processors Association.

NFPA's position on raw juice has been in place since 1996. In brief, our position is a follows: Juice or juice ingredients should receive pasteurization or an equivalent pro sufficient to render the juice or juice ingredients free of vegetative cells or microorganisms of public health significance.

Alternative processing methods that may provide an equivalent kill step include, but are not limited to, batch and continuous high-pressure processing systems, pulsed elec fields, ultraviolet light, irradiation, or perhaps even ultra-filtration, or use of on more of these preceding treatments in combination with an antimicrobial compound.

In developing this position, NFPA concluded that the only means of assuring that juice would not contain potentially pathogenic microorganisms was to include a microbial con step that has been scientifically proven to be effective in providing a level of protection equivalent to pasteurization in the process.

Our members did not feel that a warning statement was sufficient to communicate the potential for illness to young children and other populations at risk who may consume

products.

The majority of the juice industry favors mandatory pasteurization or an equivalent process to eliminate human pathogens from the product rather than an approach that wou allow hazardous product to be sold if appropriately labeled.

NFPA currently feels that only a microbial kill step applied to the juice itself can ensure that potentially pathogenic microorganisms are eliminated. There has been discussion concerning using various sorting and washing steps to achieve a 5-log reduc in potential pathogens. Sorting and washing of fruit should be standard practice in al good manufacturing practice operations for juice production, but cannot be relied upon solely to assure complete removal of pathogenic microorganisms.

While theoretically possible, achieving an appropriate level of protection from pathogenic microorganisms without applying some inactivating treatment to the juice se technologically unfeasible at this time.

To emphasize our position in this regard, theoretical techniques or, as we would like to say, unproven intervention procedures should be confined to research centers until procedures can be confirmed to result in safe products. Allowing the marketplace to be used in the context of an experiment is inexcusable.

Indeed, several studies have shown that surface treatments are ineffective in reducing microbial populations that have been internalized in produce. These microorganisms wil carried into the juice during the juice extraction process. Numerous studies have show that human pathogens can survive in both apple and orange juice despite their natural acidity.

If juice is produced with appropriate good manufacturing practices, a kill step applie to the juice, be it pasteurization or an equivalent process sufficient to achieve a 5- pathogen reduction, should be more than sufficient to eliminate any pathogenic microorganisms from the juice.

In reviewing existing information, NFPA concluded that the minimum time/temperature combinations necessary to inactivate 5 logs of vegetative pathogens in juice deserve further study. As a result, NFPA instituted research to more precisely determine the h resistance of stationary phase and--

MS. JACKSON: You have one minute remaining.

MR. MATTHYS: --acid adapted cells of E. coli 0157:H7, Salmonella, and Listeria monocytogenes in single-strength apple, orange, and white grape juices. A paper summarizing this research has been prepared for publication and is undergoing internal review. Based on the data, it appears that normal processing conditions calculated for hot-fill, shelf-stable juices achieve lethality in excess of 50,000D. That's a 50,000- reduction for shelf-stable product. That precludes the need for further microbial validation studies for these products. They are, in fact--the bottom line, if you have shelf-stable product, you are doing 100 percent incubation on that product to show tha you have achieved basically the 50,000-log reduction for pathogens because you are goi after much more heat-resistant organisms that would spoil that product. If you experie spoilage, you're still well above what you need for pathogens. You have that much of a safety margin.

Thank you for your time.

MS. OLIVER: Thank you.

Darren Mitchell? Is Darren Mitchell here?

[No response.]

MS. OLIVER: Okay. Charles Orman?

MR. ORMAN: I have to start by apologizing to Dr. Arpaia and this Committee. I gave bad information earlier today. The pH on the sodium bicarbonate in the chlorine tank is 8.

Good afternoon. My name is Charles R. Orman. I've worked for Sunkist for over 22 years primarily in the area of post-harvest, and I work with the member packinghouses advisi them on such issues as sanitation, chemical use, and temperature management. I'm also the board of directors of the California Citrus Quality Council, an organization that works to ensure acceptability of California citrus in the U.S. and around the world by offering scientific arguments to support uniform chemical sanitary and phytosanitary regulations.

My purpose in speaking here today is to address the issue of infiltration of pathogens in citrus during the fresh fruit packing process and the potential for harming the goo reputation of fresh citrus. I'll preface my remarks by noting that California and Ariz do not grow fruit for the juice market. The citrus grown in these states is produced specifically for the fresh market.

About 35 percent of our fruit is exported, primarily to the Pacific Rim nations. The balance is sold domestically. Our culls are sent to landfills or cattle feed. Fruit wh is not able to meet the cosmetic standard for sale as fresh but are still sound are se to our products plants for processing. All of the juice that Sunkist produces is pasteurized. However, a certain percentage of our fruit does, in fact, end up used for fresh juice, but it has been through the packing house procedures.

Our focus over the past 100 years has been to improve arrivals at the marketplace for fresh citrus. Our sanitation procedures and temperature regimes, which Dr. Arpaia revi earlier, are based on protecting the fruit from plant pathogens and ensuring that the best-quality fruit possible is available for everyone from Singapore to Spain.

Fortunately, these procedures or GMPs are also able to help protect from human pathogens. Dr. Ismail has indicated there has never been a case of pathogenic illness caused by citrus cited in the literature. This is testimony to the fact that the U.S. citrus industry produces a healthy product.

Tests run by the FDA on dye infiltration are fatally flawed. The conditions the tests were run under do not reflect citrus industry practice. Specifically, we do not use hydrocoolers, and the longest duration tank I am aware of probably has about three min of residence time. Our wash tanks are typically heated to a minimum of 90 degrees Fahrenheit to a maximum of 115 degrees Fahrenheit. Typically they run between 105 and degrees Fahrenheit. We would never experience a situation of dumping warm fruit into a cold tank in a citrus packinghouse.

In addition, the guiding tenet in the citrus industry is that the first water the frui is exposed to has to be sterile. The old-timers told me that this water would fill the nooks and crannies on the fruit, and if it wasn't sterile, it would carry in mold spor that subsequent applications of surface sanitizers would not be able to eradicate. Sin then we have expanded this concept to include all of the aqueous exposures of the frui the packinghouse.

It is my opinion that any of the problems associated with fresh squeezed citrus juice have been caused by poor handling practices at the juicing operation, not as a result receiving contaminated citrus.

There were four specific questions posed in the Federal Register notice, and I'd like to address those briefly now.

Is the assumption valid that there is no internalization of human pathogens in citrus? My answer is that there is no evidence that shows that there is internalization of hum pathogens in citrus.

MS. JACKSON: You have one minute remaining.

MR. ORMAN: Given packinghouse GMPs that are in place in the field and the packinghouse there is no demonstrated route of contamination and no demonstrated route of infection Human pathogens have never been shown to exist within citrus at any time and, more to point, have never been demonstrated to exist in citrus that has gone through a commerc packinghouse operation.

The rest of it is along the same lines. It's all yours. Thank you.

MS. OLIVER: Thank you.

Our next speaker is Charlene Rainey.

MS. RAINEY: I'm Charlene Rainey from Nutrition Network, and I would like to thank FDA and the Committee for giving us the opportunity to present brief public comments to yo today.

I'm representing Juice Tree, a manufacturer of juicing equipment for over 35 years and an associate member of the American Fresh Juice Council, a trade organization formed t represent the fresh juice processors. It has been Juice Tree's interest and unofficial role to represent those food service providers in both restaurants and retail location who make juice on their premises and sell directly to the consumer. In that capacity, are commenting to FDA proposed regulations on the labeling of unpasteurized juice.

My comments today will focus on orange juice and speak specifically to FDA's request o the likeliness of a public health risk. In doing so, I will make distinctions of two t of fresh squeezed orange juice and techniques used to achieve desired levels of public health safety. I will also briefly touch on some economic factors related to juice regulations.

When a consumer is purchasing fresh squeezed orange juice at a food service location, either at a restaurant or retail food service, there are two distinct types of fresh squeezed orange juice that they may be offered. One is fresh squeezed on site, and the other is unpasteurized purchased from a processing plant. Currently, the consumer has little or no way of distinguishing which type of product is being offered for sale. Th are no labeling distinctions either on the packaging or on the menu. They are both lab and sold as fresh squeezed orange juice, but these products have distinct differences their likeliness to produce public health risk.

The first, fresh squeezed juice, is on-site fresh squeezed. There are four control points about this juice that distinguish it both in safety and in its cost to the consumer: one, the fact that it is squeezed on site; two, the grade of the fruit used; three, small batch size; and, four, the length of time between squeezing and sale to t consumer.

The first distinction of fresh squeezed juice is that it is squeezed on site. The juic is not subjected to transportation and distribution steps. It is squeezed and bottled food service and retail locations and sold directly to the consumer. Sanitary conditio are closely monitored by local health officials.

In the packinghouse, fruit is separated into two distinct categories: Retail grade, which is made up of choice or fancy fruit, is selected because it is free from defects All other fruit are culled out or put in juice grade, which is sold only to processing plants, never to food service or retail. Only the retail-grade choice and fancy orange are used in food service and retail locations. Consumers purchase retail-grade fruit t squeeze fresh squeezed orange juice in home preparation. Retail-grade oranges can cost to four times the cost of juice-grade oranges sold to processors.

Small batches yield only four to eight gallons of juice in a typical on-site juicing.

Because the volume is produced on such a small scale, on-site juicing, there is usuall just enough product to serve to the customers that day. The time between juicing and t sale of on-site fresh squeezed juice is usually just a few hours but never more than 4 hours. The juice is bottled in both food service and retail locations and kept refrigerated at point of sale.

Fresh squeezed on-side orange juice has a much shorter time from squeezing to purchase because of time saved not having to transport the product. The history of public healt problems associated with fresh squeezed--

MS. JACKSON: You have one minute remaining.

MS. RAINEY: --orange juice have been associated with unpasteurized juice from processing plants. It is significant for the Committee to consider that there have bee outbreaks or recalls of on-site fresh squeezed juice. There have been no problems with consumers who are squeezing fresh juice in their homes.

We urge the Committee to suggest further distinctions should be made between the safet of on-site fresh squeezed orange juice made from premium retail-grade fruit and sold within 48 hours and the unpasteurized orange juice made from juice-grade fruit and transported from processing plants as long as weeks after squeezing.

Further research is needed on consumers' understanding of how broad the definition of fresh squeezed orange juice should be. Perhaps there is a need to clarify and narrow t definition of fresh squeezed orange juice.

Thank you.

MS. OLIVER: Thank you.

Next, Jim Rosenberg.

MR. ROSENBERG: My name is Jim Rosenberg, and I own a fresh juice company in Los Angeles. I'm also the president of the Micro Juicers Guild.

I came to Washington to fight for the freedom of choice. I don't want to be told what can't have or do for unjust reasons. Freedom of choice is why we remain loyal to our country. It's our inspiration.

Fifteen years ago, I chose to make fresh juice. I'm still doing it today. One hundred million servings later, we continue to improve our manufacturing practices in order to as safe as possible. Our track record is impeccable, as is the fresh juice industry as whole.

In 15 years, no one has ever become seriously ill from my juice. The level of responsibility that our industry has displayed is admirable. Our customers should feel proud to drink our fresh juice.

Fresh juice is special. There's nothing like it. People choose to drink and pay more for it because of the taste and nutritional value. It's a personal choice that million choose every day.

Citrus juice manufacturers hopefully will achieve what's necessary to continue to produce fresh citrus juice without having to use a warning label. Others, like my comp whose juices such as carrot, apple, and smoothies may not be able to achieve a 5-log reduction without some sort of adulteration. Our customers want only pure, unadulterat fresh juice.

My company follows GMPs, SSOPs, and has a HACCP plan that does not achieve a 5-log reduction. We have used warning labels for over a year now. We lost sales due to the warning label, but continue to thrive overall. Most likely, the particular at-risk gro

are avoiding fresh juice. The warning labels seems to be working.

All manufacturers of fresh juice must adhere to GMPs and implement SSOPs and HACCP. If a 5-log reduction cannot be achieved, a warning label should take the place of a 5-log reduction, but not take the place of GMPs, SSOPs, and HACCP. This will ensure overall safety while not shutting down the manufacturers of juices other than citrus.

In California, the compliance and inspection system needs to be improved. Those companies who are manufacturing irresponsibly need to be shut down. Those companies wh choose to be responsible and do things right have a safe product. Our track record pro it.

Nothing is 100 percent safe. The people who are fighting to shut down the fresh juice industry should think about the personal choices they choose every day that are far mo potentially dangerous to their health than fresh juice is.

Standing back and looking at the big picture, this is a circumstance in which the American people should have the right to make their own personal decision.

Safety is achieved through GMPs, SSOPs, and HACCP. If a 5-log reduction is not achieved, a warning label must be a permanent option. This will ensure freedom of choi for us all.

After all these years of continual education and improvement of manufacturing practices--

MS. JACKSON: You have one minute remaining.

MR. ROSENBERG: After all these years of continual education and improvement of manufacturing practices and nearly a perfect track record, I don't understand why something as delicious and nutritious as fresh squeezed juice would be faced with poss extinction.

Taste and then understand the difference between fresh squeezed and pasteurized juice. You will fight for the right as well.

MS. OLIVER: Thank you.

Joseph Speroni?

MR. SPERONI: Thank you and good afternoon. I'm Joe Speroni from Ocean Spray, where I'm the director of analytical food and quality sciences. As you know, Ocean Spray is a la producer of primarily shelf-stable cranberry, grapefruit, and a multitude of blended juices and juice drinks.

Ocean Spray was the first company to participate in the FDA's HACCP piloting process. We commend the agency for the opportunity to participate in this process. Furthermore, manner in which the pilots were conducted has given us and the agency an opportunity t constructively create and engage in a dialogue in a spirit of mutual alignment toward common objective, that is, improving the safety of the American food supply.

In short, why we were interested in participating with FDA in a HACCP pilot? We believ in HACCP as a system to improve food safety, and the pilot provides the forum to proactively shape the direction of HACCP in this industry.

Now, we have seen in the past how industry, trade associations, the academic community and the FDA have combined to shape and develop regulations. So-called low-acid canned regulations published during the 1970s is an excellent example. The collected and integrated work of industry, the trade associations, and FDA led to the development of highly effective regulations that ultimately standardized and improved the safety of t industry. These regulations are very similar to HACCP in philosophy and were grounded

good science.

Now, I must stress that we are only one member of the juice industry, and a large one. Other members will and should look at HACCP differently. HACCP is evolving, and these pilot programs are only part of that evolution.

We fully embrace the concepts and philosophy of HACCP, and it is a cornerstone of our quality assurance program. In fact, we use the philosophy to go beyond food safety. We think it's an excellent philosophy to control many things. However, we do not see the wisdom of extending HACCP as a regulatory tool in the shelf-stable juice industry. Instead, we offer the following five points for consideration:

First, we support mandatory pasteurization under the current GMPs. We do not say let's get lax in everything else upstream and downstream of there. In fact, we say let's get better. All juices sold commercially should be pasteurized, period.

Secondly, the concept of a 5D cumulative kill is not adequate; rather, we support a single-point intervention with a 5D kill. This kill steps must be as close to the fina consumer packaging as is possible.

Third, thermal processing has been demonstrated to be an effective and reliable contro step, but we also support using other technologies so long as they are fully validated deliver against that 5D kill or a suitable quantifiable standard measured against know relevant pathogenic organisms.

Four, for shelf-stable juices produce by the hot-fill hold process or by an aseptic process, regulating HACCP to control microbiological risk is not necessary since the h required to inactivate the yeast and mold to render it shelf-stable far exceeds that needed for pathogenic organisms. Indeed, our processes are in excess of 50,000D. You simply cannot make a shelf-stable juice without pasteurizing. You can't bake a loaf of bread without baking it. You cannot make a shelf-stable juice without pasteurizing it. we believe that juice on the dry shelves should be exempt from any of these HACCP-type regulations where you are controlling microbial risk.

Fifth, we do not support warning labels on any food where the risk is so easily controllable. However, should the agency decide not to mandate pasteurization or shoul they permit a cumulative 5D process rather than a single-point intervention, then and then those products should bear a prominent label warning consumers that they have not

MS. JACKSON: You have one minute remaining.

MR. SPERONI: --been pasteurized.

In closing, we understand that mandatory pasteurization may create financial hardships on smaller companies, but size should not matter when controlling risks to the public' health. When the so-called low-acid canned food regulations were promulgated in the 19 good science drove the process, and the industry and FDA succeeded in making the resul products much safer for our consumers. Companies' financial size was irrelevant to the minimum processing requirements. The same logic should hold for juice.

Thank you.

MS. OLIVER: Thank you.

Dave Sperry?

MR. SPERRY: Good afternoon. I'm proud to be here today to represent several different factions: first of all, California Day-Fresh Foods. California Day-Fresh is a total ju processor. We like to say that we actually squeeze, press, and blend all under one roo So whereas fresh citrus is a big part of what we do, we also do just about every other type of juice. Our products are distributed primarily in the 14 Western states and

predominantly under the Naked name.

We are also proud to have had the opportunity to participate in the Fresh Juice Consortium that you saw the results of today, and we're also proud to be a member of t American Fresh Juice Council.

I want to kind of tag on to Dr. Ismail's comments from this morning that says we ought to look at this from the perspective of both sound science but also common sense. At California Day-Fresh, we first of all firmly believe that fresh juice is safe. We also would support increased plant inspections, as has also been alluded to today.

We propose that all juice processors, regardless of technique, should be required to operate under a HACCP plan based on the Florida model that was discussed today.

Pasteurization is not a cure-all. Improved handling--actually, improper handling could potentially result in the reinfection of pasteurized juice.

We as a company, California Day-Fresh, have made a significant investment to date, bot in the form of R&D and also in capital, to comply with the existing HACCP proposal, which I think we all agree now would certainly at best appear to be very much of a mov target.

There has not been any real-world documented case of fruit internalization. We currently--as the Fresh Juice Company indicated earlier, in our food safety program we current test, hold, and release, as we test for both Salmonella and pathogenic E. coli There continues to be a strong growing demand for fresh, better-tasting, and more nutritious juice.

Now, having said all that, I can't resist this opportunity to make my attempt to answe the four questions for you, so bear with me, from a science and common-sense perspecti

A, is it valid to assume that there is no internalization of pathogens in citrus fruits? Evidence, or lack thereof, in conjunction with years of negative testing exhib today, suggests that the answer to this is yes.

Is internalization of pathogens into citrus fruit theoretically possible? It is theoretically possible, and as we have heard, probable if artificially introduced to t porous surface of fruit.

If internalization of pathogens into citrus fruits is theoretically possible, is such internalization likely to result in a public health risk? There is no zero level of ri when consuming any food product, regardless of process. If internalization does occur, research has shown that it does not represent a significant public health risk.

And, D, if internalization does occur and results in a public health risk, are there techniques to assure that internalization of pathogens do not occur? And if so, what a they? We believe, as I said earlier, that the adoption of procedures such as the Flori HACCP plan represent just that type of opportunity.

Again, I want to thank you for the opportunity to speak before you today.

MS. OLIVER: Thank you.

Leslie Zinn?

MS. ZINN: Hi. My name is Leslie Zinn, and I own a small juice company located in Atlanta, Georgia.

I was fortunate to have grown up drinking fresh fruit and vegetable juices because my mother was devoted to her children's health and firmly believed in sound nutrition tha nourished our bodies.

In 1994, my brother, mother, and I decided to open a fresh juice company because we knew firsthand the health benefits of fresh juice, and we wanted to offer these benefi to others. Our business grew very quickly because there was and is a strong demand for fresh products.

In October of 1996, when the Odwalla outbreak took place, we lost our biggest customer the Kroger Food Company. At that time it would have been in our business' best interes pasteurize our product. We would have been able to extend our shelf life, increase our distribution, and retain our large customers. However, we chose not to pasteurize beca there is a difference between fresh and pasteurized, and the difference is not only ta The difference is enzymes.

I'd like to quote from the book "Enzymes, The Fountain of Life" by Dr. Lopez from UC-San Diego and Dr. Williams from Northwestern University. They say: "Why are enzymes important to us? To an amazingly large extent, enzymes are responsible for our health. Biochemists have described them as the body's labor force or the life energy o all organisms. And yet, medicine has paid only limited attention to these vital compon of our bodies."

They go on: "The naturally occurring enzymes we eat in fresh and raw foods are also of great importance. What enzymes these are and in what quantity depends on the t of food and the state in which the food is eaten. For instance, fresh naturally ripene pineapples are rich in the protein-splitting enzyme bromelin, although scarcely any ca found in canned pineapples. In learning to heat and cook foods, our forefathers have probably done our tongues and teeth a favor. But they have done less for our digestive systems and health since heating destroys virtually all the enzymes in our food."

Unlike Ms. Girand, who shared her tragic stories that were caused by negligent manufacturing, I have stories of hope and recovery. There are individuals with cancer, AIDS, ovarian cysts, and other maladies who choose to use fresh juice to boost their immune systems and improve their health. I have brought a video of one such individual wanted to share his story with you all.

[Video shown.]

MS. ZINN: The question, I believe, that you are being asked to consider is that of public health. The two leading causes of death in the United States, heart disease and cancer, both have large nutritional components. Many ongoing cancer research studies a finding benefits directly attributed to fresh fruits and vegetables. Obesity is one of five major factors contributing to heart disease. My home state, Georgia, had a 100 percent increase in obesity in the last 10 years. People are looking for answers and e of use to improve their health. Fresh juices provide both.

Getting rid of fresh juice is not in the public health's best interest. Good sanitary practices, implementation of HACCP, and increased inspection are what is needed to ens the safety of fresh juice. Our country is the most overfed, undernourished country in developed world. Our citizens deserve the right to choose if they want to buy fresh products, including fresh juice, fresh cut, and fresh produce. Please do not deny this freedom.

Thanks.

[Applause.]

MS. OLIVER: Thank you.

Before I go on to our next group, I'd ask if Darren Mitchell is here yet.

[No response.]

MS. OLIVER: Okay. The next group of speakers each have two minutes. The first is Richard Kinney.

MR. KINNEY: Good afternoon. I'm Richard Kinney. I work for Florida Citrus Packers. We're a trade association of fresh citrus packinghouses.

It seems to us the Committee is considering two grave and weight issues today, and the question is as to whether or not fresh squeezed orange juice is safe, and in your decisionmaking regarding that issue, you could put a lot of people out of business. Bu regarding the latter, please understand that fresh squeezed processors do not have a one-time treatment as an alternative.

Under FDA's own standard of identity for fresh, as we understand it, pasteurization or some other alternative that achieves that 5-log after extraction is considered an addi and, therefore, would redefine fresh squeezed juice in the processed category. You cou no longer use the word "fresh." And, obviously, if fresh squeezed loses that clear and distinct differentiation between fresh and processed, then that puts us in a whole new category. And marketing-wise and quality-wise, we lose the most important attribute of fresh squeezed, and that's the use of the term "fresh." And, frankly, our competitors, the processors, would love for you to make that decision bec they know it would put us out of business.

But, first and foremost, you have raised the issue as to whether or not fresh squeezed orange juice is safe. Is there a risk to the public when appropriate sanitation measur are applied to the production of fresh squeezed orange juice? And the answer to that question is no, for these reasons: six instances in 55 years and a compelling body of evidence that suggests there was a breakdown in procedures and handling; and, secondly the research that you're considering on dye penetration and pathogen uptake, the scientists that we talked to that have reviewed that data and that information use the terms, "highly artificial," "flimsy basis," "extremely theoretical."

We think that that research is suspect and very flawed. But there is compelling, if no overwhelming evidence that addresses the real-world question. The real-world question: What is the probability of finding pathogens on or in oranges arriving at the plant an just before extraction? Seventeen thousand batches of juice tested, billions of pieces fruit in that juice, no E. coli, no Salmonella. It doesn't happen. The evidence to us very compelling and very clear.

Thank you.

MS. OLIVER: Dick Germond?

MR. GERMOND: Good afternoon. I'm Dick Germond. I'm quality and food safety manager at Perricone Juice in California.

Ladies and gentlemen of the Committee, as I was pondering what I was going to use my two minutes to say to try and impact your deliberations tomorrow, I thought of Ms. Gir I thought of my daughter, my family. I thought of what our company does to ensure the manufacture of a product. I thought: Do I start to tell you about the capital improvem our company has made? About the better equipment, better facilities? The increased amo of testing that we do? An incredible increase. I thought about our sanitation program, GMPs that we've written and implemented, HACCP.

What could I say that could have an impact? Come to our plant? No time. But please do if we're still here.

I wasn't sure what I was going to say until I thought I need to appeal to each of you serving this Committee. It's the smallest functional unit of our government. I believe as a company, as an industry, are making safe juice. Today we are not opposed to regulation, if it's not misguided. We need oversight and we need enforcement.

I believe in our system of government. I believe in you, the Committee. I believe in science. I believe in you, the scientists. I believe good guys do win in this country.

We're trusting in your integrity and in your deliberations as scientists and members o this Committee.

Thank you.

MS. OLIVER: Thank you.

Robin Prever?

MS. PREVER: Good afternoon. Robin Prever, Saratoga Beverage Group. I'm going to speak really fast.

First of all, I'd like to say we share the concern with both the FDA and the STOP organization regarding food safety. We understand the pressure the Committee is under light of the recent Sun Orchard incident. I have a copy of the letter that the FDA had sent to Mark Isaacs, the president of Sun Orchard. If anyone would like to see a copy that, I can leave it in the back.

We respectfully request that you punish the negligent food and beverage producers, not the entire industry. Please, enforce the standards that will prevent foodborne illness forcing HACCP. Pasteurization is just not the answer.

We've been producing safe fresh citrus juice for over 10 years, 250,000 gallons a week to be exact. I'd like to illustrate a few points.

First of all, both our California and our Florida facility complies with the Florida HACCP model. We grade all of our fruit. We have a zero tolerance on fruit. We test eve single batch of juice that we make. We have a 24-hour hold. Juice does not leave our facility until we get a negative result on our testing.

We are part of the consortium that Dr. Strobos referred to before, four competitors that are working together to demonstrate our safety record. A member of this Committee referred to our group as exemplary. I would say we're not exemplary, but we're conscientious. We're honest manufacturers that are committed to quality and safety.

Fresh juice is truly a delicacy. Once you've tried fresh squeezed orange juice, it's really impossible to go back to pasteurized juice. It's the most natural form of orang juice consumption. The delicate flavor and the vitamins are dramatically affected by h processing. There will always be a fresh juice consumer. By forcing the commercial fre juice companies that operate under HACCP plans out of business, all you will do is pro and encourage a proliferation of in-store producers which may or may not be affected b the FDA regulations.

Pasteurization is not the solution. Bad manufacturers will continue to manufacture bad products. Please, mandate the Florida HACCP model, and based on what Dr. Ismail said before, six occurrences have occurred in the past 45 years, every single one of them t to the lack of GMPs, not tied to the orange.

Please, regulate, don't exterminate this industry. Thank you.

MS. OLIVER: Thank you very much.

That was the last of our public commenters, and it's just about 5 o'clock and we're scheduled to adjourn. So I think we'll adjourn for the day.

We'll begin tomorrow morning at 8 o'clock, and I don't know if we had additional paper or if we copied all of the papers for our Committee. Kathy, have we copied them?

[Pause.]

MS. OLIVER: All the papers we have have been copied and distributed, so we'll see you here tomorrow morning at 8 o'clock.

Thank you very much.

[Whereupon, at 4:50 p.m., the meeting was adjourned, to reconvene at 8:00 a.m., the following day, Thursday, December 9, 1999.]

Home | HACCP

Hypertext updated by ces/cjm/ear/dms 2000-JAN-27